Abstract

MEDICAL FAMILY THERAPY MEETS CHILDHOOD OBESITY

by

Keeley J. Pratt, M.S., Doctoral Candidate

March 3, 2010

Chair: Angela L. Lamson, Ph.D.

Major Department: Child Development and Family Relations

The dissertation is a compilation of two journal articles. The first article is a literature review that addresses integrated care for childhood obesity with consideration for clinical, operational, and financial practices. The purpose of the first article is to explore the evolution of pediatric care for children who are overweight by addressing: 1) terms, recent expert recommendations, 2) a structure for synthesizing clinical, operational, and financial practices, and 3) recommendations that bridge medical and other healthcare options for pediatric overweight patients and their families. The second article is an exploration of longitudinal systemic experiences of childhood obesity with children and their families who participated in research at the Pediatric Healthy Weight Research and Treatment Center. The purpose of this article is to identify changes in outcomes from initial visits at the PHWRTC to follow-up visits. In addition, we explored variables associated with or predictive of the variability in changes from the initial visits to follow-up visits. Outcomes for children and caregivers included: quality of life, depression, and relative body mass index.

Medical Family Therapy Meets Childhood Obesity

A Dissertation Presented to

the faculty of the Department of Child Development and Family Relations

East Carolina University

In Partial Fulfillment of the

Requirements for the Degree Doctor of

Philosophy in Medical Family Therapy

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Dedication Page

I dedicate this dissertation to the Pediatric Healthy Weight Research and Treatment Center, the patients and families seen at the center, and my mentors and colleagues: Dr. Suzanne Lazorick, Dr. David Collier, Dr. John Olsson, Sarah Henes, Yancey Crawford, and Joy Aycock who have provided me with experience, support, and encouragement as we together work with our families to fight childhood obesity.

ACKNOWLEDGEMENT

Because it takes a village…

First and foremost, I would like to thank my parents for encouraging me to pursue my passions, especially those new and different, from anything anyone in our family has previously done. By proximity I have been more distant than ever living in North Carolina, however your support and love couldn't have been stronger over the years. Thank you for continuing to be curious about what I am doing and sharing in the excitement every step of the way.

Secondly, I would like to express my gratitude to my major advisor, supervisor, mentor, and at times stand-in life coach Dr. Angela Lamson, for her unwavering support and encouragement over the past five years. I have learned so much about myself and the type of person and professional I will strive to be because of your mentorship. Thank you for encouraging me to pursue my interests in childhood obesity and pediatrics and to find others who can match my energy along the way.

I would like to acknowledge Dr. John Olsson, Dr. Suzanne Lazorick, and Dr. David Collier who have graciously become my "medical mentors" over the years. I couldn't have asked to be part of a more dedicated, compassionate, and energetic treatment team.

I would like to thank my dissertation committee: Dr. David Collier, Dr. Suzanne Lazorick, Dr. Melvin "Mel" Swanson, Dr. Carmel White, and Dr. Mark White for their keen editing skills, interest, and assistance during the dissertation process.

I would like to express my gratitude to the Family Therapy Faculty at ECU, specifically Dr. David Dosser and Dr. Mel Markowski who have provided me with countless life-lessons about being a therapist, professor, and a healthy professional during my master's and doctoral experience.

I would also like to thank the Chairs in the Departments of Child Development and Family Relations, Dr. Cynthia Johnson, and Pediatrics, Dr. Ronald Perkin for their continued support and enthusiasm for Medical Family Therapy (MedFT) and its benefit in Pediatrics.

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Preface

As long as I can remember, I have been interested in health and working with children. These interests led me to pursue work experiences and academic courses at the bachelors, masters, and doctoral level to develop a foundation for the overall health of children and families. In the first year of my masters program in marriage and family therapy, I was presented with the opportunity to intern at the Pediatric Healthy Weight Research and Treatment Center (PHWRTC). The PHWRTC was created to meet the demands of the childhood obesity epidemic in North Carolina (NC). NC has been significantly affected by childhood obesity with the percentage of children who are overweight (19.3%) exceeding that of the national average (14.8%) (U.S. Department of Health and Human Services (DHHS), Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB), 2005). Specifically in eastern North Carolina, where the PHWRTC is located, half of school-age children are either overweight or obese (Crawford, 2006). The PHWRTC has brought together professionals from East Carolina University who are passionate about reducing childhood obesity via collaboration in clinical care and research. The PHWRTC multidisciplinary team has included pediatricians, physical therapists, family therapists (Marriage and Family Therapist and Medical Family Therapists), a dental periodontist, and a dietitian/nutritionist.

Shortly after I began my internship at the PHWRTC my passion for childhood obesity was ignited. After just a couple of months, I became engrossed with two distinct areas of pediatric obesity. The first area that I became interested in was the role that obesity played in families. For example, I began to realize that eating and activity patterns were similar among children and their caregivers. As a family therapist, the systemic dynamics associated with lifestyle changes, specifically related to nutrition and physical activity, had to be assessed and

managed via the family's past and present experiences with weight and its biopsychosocial implications. With the help of my advisor, Dr. Angela Lamson, we selected clinical assessments pertaining to quality of life and depression that had sound psychometrics for use with children and caregivers, which could be disseminated and analyzed at each PHWRTC visit. The more experience I gained as a clinician and researcher, the more questions I had about the systemic implications for children and their families.

My second area of interest with the PHWRTC has been with the exploration of policy and reimbursement for family therapy services. Throughout the past three years with PHWRTC, I began to wonder more about the influence of policy/procedures and reimbursement in relation to clinical care delivered by multidisciplinary providers and integrated care treatment teams.

This dissertation seeks to address these two areas of interest, among others. The dissertation is a compilation of two journal articles. The first article is a literature review that addresses integrated care for childhood obesity through the three-world view (Patterson et al., 2002) as described by clinical, operational, and financial procedures. The purpose of the first article is to explore the evolution of pediatric care for children who are obese and overweight by addressing: 1) terms, recent expert recommendations, and the implementation guide pertaining to pediatric obesity treatment, 2) a structure for synthesizing clinical, operational, and financial practices through the three-world view, and 3) recommendations that bridge medical and other healthcare options for pediatric overweight patients and their families.

The second article is a study based on an exploration of longitudinal systemic experiences of childhood obesity with children and their families who participated in research at the PHWRTC. The purpose of this article is to identify changes in outcomes from initial visits (V1) at the PHWRTC to follow-up visits Visit two (V2) and Visit three (V3). In addition, we

explore variables that are associated with or predictive of the variability in changes from initial visits to follow-up visits. Outcomes for children and caregivers include: quality of life, depression, and health status in relation to contextual variables. The health status and contextual variables consist of: 1) sex, race, and age, 2) family structure breakdown, 3) and for child only, body mass index (BMI), BMI z-score, percent overBMI, and BMI category

Abstract

CONCEPTUALIZING CARE FOR CHILDHOOD OBESITY THROUGH CLINICAL, OPERATIONAL, AND FINANCIAL PROCEDURES

by

Keeley J. Pratt, M.S., Doctoral Candidate

March 3, 2010

Chair: Angela L. Lamson, Ph.D.

Major Department: Child Development and Family Relations

This manuscript is a review article regarding care for overweight/obese children and their families through synthesizing treatment in the clinical, administrative/policy, and financial domains as organized by C.J. Peek's Three-world view. Additionally, the article traces the trajectory of pediatric obesity care from initial musings, to family-centered care, multidisciplinary care, and the most recent recommendations (as stated by the Expert Committee) for treatment. The purpose of this review is to bring together and inform multiple disciplines about 1) terms, recent expert recommendations, and the implementation guide pertaining to pediatric obesity treatment, 2) a structure for synthesizing clinical, operational, and financial practices, and 3) recommendations that bridge medical and other healthcare options for pediatric overweight patients and their families.

*Submitted to *Journal of Children's Services* on 11/2/09.

Chapter 1: Conceptualizing Care for Childhood Obesity through Clinical, Operational, and Financial Procedures

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Introduction/Purpose

The landscape of pediatric healthcare is changing with increasing demands to address serious chronic conditions for the youngest of patients and their families. The disciplines of pediatric healthcare providers (e.g., physical therapy, dentistry, nutrition, behavioral health, social work) and their various professional roles (e.g., trainer, provider, policy maker, and researcher) continue to change and increase (Katz & Faridi, 2008). This transformation in pediatric healthcare and treatment teams may in part be due to the evolving needs of pediatric patients and their families. Adjustments in pediatric treatment, research, and policy are now incorporating not only the child's needs, but also those of the family.

Taking these dynamics into consideration, the focus of this article will be on overweight and obese children and the multifaceted needs and risks faced by these children and their families. Overweight and obese children are at an increased risk for many medical comorbidities such as type 2 diabetes, heart disease, high cholesterol, hypertension, early puberty, enuresis, polycystic ovarian syndrome, and sleep problems (Dietz, 1998; Kiess et al., 2001, Institute of Medicine [IOM], 2005; *Overweight and Physical Activity among Children: A portrait of states and the nation*, 2005) as well as psychosocial comorbidities that include poor self-esteem, low self-worth, depression (IOM, 2005; Speiser et al., 2005), loneliness, poor self image, auto-aggression, suicide, drug and alcohol addiction, bulimia, binge eating, and smoking (Hoot & Lynn-Garbe, 2005; Kiess et al., 2001; *Overweight and Physical Activity among Children: A portrait of states and the nation*, 2005).

Specifically, the purpose of this article is to explore the evolution of pediatric care for obese and overweight children by addressing: 1) terms, recent expert recommendations, and the implementation guide pertaining to pediatric obesity treatment; 2) a structure for synthesizing

clinical, operational, and financial practices through the three-world view, discussed further below (Patterson, Peek, Heinrich, Bischoff, & Scherger, 2002); and 3) recommendations that bridge medical and other healthcare options for pediatric overweight patients and their families.

One inherent challenge in synthesizing pediatric obesity research is finding shared definitions for terms describing types of care. Throughout this article, terms will be referenced related to philosophy to and methods of treatment. To begin, the context of this article is grounded in a philosophy to treatment known as the three-world view (Peek, 2002). These terms necessitate an operational definition to assume consistency in understanding throughout the article. The three world view of C.J. Peek informs us that healthcare settings, including pediatric obesity treatment programs, face three simultaneous challenges (a) the clinical challenge to provide exceptional patient care; (b) the operational challenge to employ efficient, well-integrated, and patient-friendly systems of care; and (c) the financial challenge of staying financially feasible and utilizing health care resources (Patterson et al., 2002). Peek (2002) called these three distinct challenges “world views.” In the three-world view it is important to look at each world in relation to the others, because no one world can function independently from the others, and no one world is considered more important than another. Other key terms include: family-centered, coordinated services, co-located services, collaborative care, integrated care, and behavioral health and medicine (see Table 1). Definitions are provided in Table 1 based on their respective disciplines and existing childhood obesity research. It is important to note that the operational definitions are not mutually exclusive. Each of the terms in Table 1 includes a definition and one example of how that type of care may occur in practice. These types of care are then applied to the description of the expert recommendations and implementation guide and

also ground the recommendations for future clinical, operational, and financial components of pediatric obesity treatment.

Expert Recommendations

In 2005, the American Medical Association (AMA), Health Resources and Services Administration (HRSA), and Centers for Disease Control and Prevention (CDC) brought together an expert committee including representatives from the areas of medicine, mental health, and epidemiology to develop recommendations for the care of overweight and obese children (Barlow, 2007). The report entitled *Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity* (2007), summarizes the findings of the Expert Committee of currently accepted practices for pediatric obesity prevention, assessment, intervention, and treatment. A concurrent publication by the National Initiative for Children's Healthcare Quality (NICHQ) entitled *An Implementation Guide from the Childhood Obesity Action Network* offers a combination of important aspects of the expert recommendations with real-world practice tools identified from primary care groups who have developed obesity care strategies (NICHQ, 2007). Thus, the implementation guide offers suggestions and tools for practical application of the expert recommendations. The expert committee recommendations describe prevention strategies that are recommended for all children and four stages of childhood obesity treatment: 1) prevention plus; 2) structured weight management; 3) comprehensive, multidisciplinary intervention, and 4) tertiary care intervention (Barlow, 2007). The recommendations below pertain specifically to pediatric obesity through preventive care to surgical treatment options.

A prevention or stage one "prevention plus" visit most commonly takes place at a child's primary care office during a yearly well care visit. At a stage one well care visit the following are

to be included by the healthcare provider: plot a body mass index (BMI), identify a weight category (i.e., underweight <5%ile, healthy weight 5-84%ile, overweight 85-94%ile, obese 95-98%ile, and ≥ 99%ile), measure blood pressure, take a family focused medical history, take a focused review of systems, perform a thorough medical physical examination, order appropriate laboratory tests, and give consistent evidence-based messages for physical activity and nutrition. For stage one, providers are also recommended to assess beyond dietary and physical activity behaviors by looking at the child's attitude including self-perceptions or concerns about weight, readiness to change, successes, barriers, and challenges (Barlow, 2007; NICHQ, 2007; Spear et al., 2007). Finally, it is recommended that the physician follow certain communication strategies (i.e., empathize, elicit, and provide) to improve the effectiveness of counseling.

Stage two, structured weight management visits take place at a primary care office with the added support of a healthcare provider who has specific training in weight management. Visits provide an increase in structure and support, specifically toward setting physical activity and nutritional goals and creating rewards. Stage two visits ideally occur on a monthly basis either with the child seen individually or as part of a group visit.

Stage three, comprehensive, multidisciplinary intervention goes beyond stage two by employing multidisciplinary childhood obesity treatment and a structured behavioral program (e.g., negotiating and reinforcing positive healthy behaviors). Ideally, families are seen weekly for 8-12 weeks with additional follow-up services.

Stage four, tertiary care intervention, is aimed at severely obese youth by utilizing treatments such as medications (e.g., Sibutramine or Orlistat), very-low calorie diets, and/or weight control surgery (i.e., Gastric Bypass or Lap-band) in addition to behavioral treatment. Thus obesity can occur in traditional "one on one" medical encounters in a primary care context

but also can evolve to multidisciplinary and collaborative care. The history and evolution of these diverse treatment modalities are described below.

Traditional Pediatric Obesity Care Treatment

Since 1957 obesity has been identified by researchers as an established pediatric condition (Gordon & Hill, 1957). At that time, the traditional treatment of pediatric obesity was done in a primary care context where children and their families likely had encounters with a single healthcare provider (i.e., a pediatrician) (Gordon & Hill, 1957) and may have had limited access to other healthcare professionals, such as a nutritionist/dietician or a behavioral healthcare provider. A traditional encounter focused primarily on the biological symptoms presented and rarely focused on behavioral changes. Any additional services needed were coordinated, but not typically co-located, with information exchanged at best from one treatment setting to another via letter, telephone, and later electronically. In the most traditional treatment, a child was the identified patient and parents were often not included in specific goals or treatment plans.

However, later in the second half of the twentieth century family-centered care began to emerge (AAP, 2007). Specifically, since at least 1976 obesity has been viewed as a familial disorder (Garn & Clark, 1976) and family-centered treatment for childhood obesity has become a documented treatment approach (Epstein, Rocco, Roemmich, & Beecher, 2007). Edmunds, Waters, and Elliot (2001) stated that the family has proven to be the most appropriate environment for the treatment and prevention of childhood obesity. Providers who used family-centered childhood obesity treatment tended to view the family as the identified patient and thus included them in goals and treatment plans.

Family-centered care is alluded to for all healthcare providers in the recent obesity care recommendations for all four of the stages of care. Overweight and obese children and their

families have complex needs that demand family-centered care, and at later stages require multidisciplinary and collaborative group of providers who can work on their behalf.

A Shift to Multidisciplinary, Collaborative Care

In the pediatric literature, multidisciplinary care for obesity (in nonsurgical programs) was not explicitly stated as an essential element until the 2007 recommendations that now lists health professionals such as dieticians, psychologists, and health educators as helpful in childhood obesity treatment from structured weight management (stage two) encounters in a primary care context through tertiary care intervention (stage four) (Barlow, 2007; NICHQ, 2007). Although there are researchers who have provided evidence for using a multidisciplinary team (Epstein et al., 2007; Fickel, Parker, & Yano, 2007; Flodmark, Lissau, Moreno, Pietrobelli, & Widhalm, 2004; Hunter & Larrieu, 1997), the previously published recommendations from American Academy of Pediatrics (AAP) and Agency for Healthcare Research Quality (AHRQ) in the United States did not emphasize multidisciplinary care for children. For example, Plourde (2006) contended "mild uncomplicated obesity can usually be managed in primary physicians' offices. [Only] patients presenting with obesity-associated comorbidity require more intensive multidisciplinary treatment" (p. 327). Therefore, based on the expert recommendations, implementation guide, and authors such as Plourde, it appears that only after a child has failed at weight-loss or maintenance in primary care that multidisciplinary providers are pursued. A challenge associated with this practice is that when children and families finally come to receive multidisciplinary healthcare services, they may already be viewed as "unsuccessful" or "noncompliant" from the first intervention attempted with their primary care provider.

Interestingly, an international perspective on childhood obesity treatment, as stated by the European Childhood Obesity Group, is that multidisciplinary programs are needed with family

involvement because treatments that include diet, exercise, behavioral therapy, surgery, and medication fail to be effective in isolation of one another (Flodmark et al, 2004). The group contends that treatment needs to be "supporting and long lasting" (Flodmark et al., 2004, p. 1192), including psychological factors as an essential element in treatment, as children are maturing (Flodmark et al., 2004). In fact, the National Institute of Health (NIH) and the Institute of Medicine (IOM) have suggested that all adult obesity treatment programs (specifically for surgical treatment) involve multidisciplinary (e.g., behavioral, nutrition, and exercise) providers (Hunter & Larrieu, 1997). The need for involvement of providers from different disciplines in order to treat pediatric obesity is being established, yet there is no clear method for how multidisciplinary providers would work together, communicate, and deliver services.

It is important for healthcare professionals to clarify that collaborative care means something specifically different than just communication among various providers (which some label as collaboration). Collaborative care is the explicit partnering of a behavioral health and medical providers in the care of a patient. Unfortunately, this distinction is not reflected in the current literature and researchers often use the following terms interchangeably: collaboration, collaborative care, and multidisciplinary care. Establishing a unified or standard definition for these terms would assist healthcare providers, researchers, and policy makers in constructing and analyzing best practices and conducting research in childhood obesity treatment programs.

Providers may represent different areas of healthcare expertise, but the way they communicate with one another, release and share information, and provide care plans is indicative of the degree to which multidisciplinary treatment is provided (National Initiative for Health Care Management, 2005). Ginsburg (2008) reviewed four dimensions that one should consider when determining the level of collaboration at a co-located pediatric practice: (a)

organizational characteristics, (b) responsibility for patients, (c) coordination mechanisms, and (d) data systems and policies. Organizational characterizes include business arrangements (e.g., contracts and agreements and administrative and financial services). Providers may have different expectations about how collaborative care is achieved or sustained. In a collaborative co-located setting, the responsibility for a patient is shared among providers ("our" patient) (Fickel et al., 2007) whereas in a less collaborative setting a provider may feel as though they are assisting with another provider's patient ("their" patient) (Ginsburg, 2008). Coordinated mechanisms involve levels of patient care and communication between providers (e.g., referrals, case reviews, and treatment plans) (Ginsburg, 2008). Data system and policies vary in how shared electronic records and data are maintained (Ginsburg, 2008). It is important to note that the recent expert recommendations do not address how collaboration should occur at the various stages of obesity treatment, nor do the recommendations outline criteria for communication among the multidisciplinary team of providers in levels two through four.

Integrated Care

One intense form of collaborative care is known as integrated care. However, there are roadblocks to initiating integrated care in a system because of the lack of clear and effective models for childhood obesity treatment and financial feasibility (Hunter & Larrieu, 1997). The lack of formal guidelines and standardized evaluation for childhood obesity programs is influencing some leaders in the field to advocate for an accreditation process similar to that in academia and hospitals for adult weight-loss programs (Stern et al., 1995). No specific call has been made for an integrated care model to become the standard for childhood obesity.

Caprio (2006) observed that the most effective obesity treatment programs have been carried out in academic centers via an approach combining nutrition, behavior modification,

physical activity, and parent involvement (Caprio, 2006). However, such treatment approaches have yet to be translated into the primary care setting. Caprio also states that successfully treating obesity "… will require a major shift in pediatric care that builds on the findings of these academic centers regarding structured intervention programs" (p. 213). Academic centers have been leading the way in the evolution of pediatric obesity services, in part because of funding, access to free or affordable student services, and the close proximity of diverse healthcare providers. However, as Caprio pointed out, it will be essential to make such programs and services transferable to a variety of settings and patients beyond academic environments. Until clear and effective models of collaborative, multidisciplinary, and family-centered treatment are provided, it will be difficult to capture what is happening in healthcare settings with regard to childhood obesity (e.g., what patients and families are experiencing at encounters, what a team is providing and how, and holding team members and childhood obesity programs accountable for quality treatment).

It is clear that settings will demand different level of collaboration, and for some settings integrated care may not be feasible. However, in order to explore if such care may be feasible, the healthcare setting needs to be assessed according to its clinical, operational, and financial components. One way to assess these components of the setting is by applying the three-world view of C.J. Peek (Patterson et al, 2002). The next section of this paper describes the evidence for clinical methods and outcomes, operational (administrative procedures), and financial features of childhood obesity using the three-world view.

The Three-world View & Childhood Obesity

The clinical, operational, and financial worlds all have their own respective internal logic and language (Patterson et al., 2002). For example, the focus in the clinical world is on treatment

plans and interventions for patients and families with an emphasis on quality, health outcomes, and goals. “Goals in the clinical world are quality and elegance” (Patterson et al., p. 35). In the operational world, services focus on “the operational systems needed to produce services, with the goals centering on efficiency and facility” (e.g., patient scheduling and flow) (p. 35). The financial world pertains to “utilizing resources and value with an emphasis on business goals and process and accounting” (p. 35). “The goal for the financial world is having the right price and good value” (p. 35). To be a successful program, actions and designs must satisfy all three-worlds (Patterson et al.).

The Clinical World of Childhood Obesity

Regardless of the stage of treatment (i.e., prevention to tertiary care) the childhood obesity clinical world is based on provider and patient interaction and thus, the first factor to consider is the provider-patient relationship. Inherent in the dichotomy of the provider-patient relationship is the patient’s past and present relationships and experiences (either negative or positive) with healthcare providers, teams, and settings. Therefore, in the clinical world it is essential to explore the potentially negative experiences that patients may have had in other healthcare contexts, specifically around weight bias and stigmatization from providers. Recently the journal *Obesity* (November, 2008) devoted an entire issue to weight bias, with six articles focusing on youth. Children are specifically identified as being vulnerable to the effects of weight bias (Puhl & Latner, 2007). Unfortunately there are only a few researchers who have published on weight bias across the lifespan (Puhl & Latner, 2008), making it difficult to predict what biases a family (and the individuals that make up a family) has experienced prior to current treatment.

Parents of obese children report feeling blamed for their child's weight and dismissed by their healthcare providers (Edmunds, 2005). Weight bias has been documented among physicians (Campbell, Engel, Timperio, Cooper, & Crawford, 2000; Hebl & Xu, 2001; Kristeller & Hoerr, 1997; Maiman, Wang, Becker, Finlay, & Simonson, 1979; Price, Desmond, Krol, Snyder, & O'Connell, 1987), medical students (Blumberg & Mellis, 1980; Keane, 1990; Wigton & McGaghie, 2001), dieticians (Berryman, Dubale, Manchester, & Mittelstaedt, 2006; McArthur & Ross, 1997; Oberrieder, Walker, Monroe, & Adeyanju, 1995), nurses (Bagley, Conklin, Isherwood, Pechiulis, & Watson, 1989; Hoppe & Ogden, 1997; Maroney & Golub, 1992), and psychologists (Amici, Thurston, & Gorsuch, 2001; Davis-Coelho, Waltz, & Davis-Coelho, 2000). In their initial interactions, healthcare providers' sensitivity with patients may assist in building a trusting patient-provider relationship whereby care is well received at any stage of treatment.

Part of emphasizing the patient-provider relationship is demonstrating the need for all members to be part of treatment (i.e., family-centered). There are inherent benefits to treating a family rather than a child in isolation. For example, Epstein, Rocco, Roemmich and Beecher (2007) noted that, "Obesity runs in families, it has been hypothesized that targeting eating and activity change in the child and parent, along with teaching parents behavioral skills to facilitate child behavior changes, could mobilize family resources to improve the efficacy of childhood obesity treatments" (p.381). The benefits of treating children and family members simultaneously may also create positive relationships between the child and parents' weight change (Wrotniak, Epstein, Paluch, & Roemmich, 2004, 2005), including parental nutrition and physical activity behaviors. The working group on National Heart Lung and Blood Institute (NHLBI) Future Research Directions in Childhood Obesity Prevention and Treatment (2007)

highlighted three main recommendations for behavioral and lifestyle interventions to treat obese children: “1) identify family dynamics which predict success of certain interventions and changes in family dynamics and relationships that are associated with favorable treatment outcomes; 2) identify utility of and methods for promoting self-monitoring of target behaviors by parents and children; and 3) investigate strategies to effectively recruit families into family-centered interventions” (National Heart Lung and Blood Institute, 2007, p. 7).

Family-behavioral treatments have been documented to be an effective strategy for weight-loss in children (Edmonds et al., 2001; Young, Northern, Lister, Drummond, & O’Brien, 2007), and are listed in the expert recommendations for stages three and four (structured comprehensive multidisciplinary intervention and tertiary care intervention). In a recent meta-analysis of 16 studies, interventions that included a family-behavioral component produced larger effect sizes than interventions without a family-behavioral component (Young et al., 2007). Epstein et al. (1994) found that behavioral family-centered treatment, which emphasizes reinforcement for child and parent behavior changes and weight loss, may have lasting effects into young adulthood. Issues such as readiness to change, parenting skills (e.g., use of praise, rewards, and discipline), and healthy role-modeling are important components in family-centered childhood obesity treatment (Connolly, Gargiula, & Reeve, 2002).

Although there is extensive literature about childhood obesity clinical interventions (whether they be diet, activity, or behavior based), only some examine the degree of family involvement (specifically through parents) or appear to be family-centered and involve multidisciplinary members in treatment teams, such as nutritionists, physicians, psychologists, and exercise physiologists. What appears to be lacking in the current clinical world is a way to

organize team collaboration in an operational way (e.g., a family-family centered and integrated care protocol) to specifically meet the needs of children and families struggling with obesity.

The Operational World of Childhood Obesity

Inherent in the settings and the intensity of a clinical intervention are the operations and organization in which the intervention is delivered. Patients spend minimal amounts of time in medical systems; instead spending the majority of their time in environments that have unhealthy food choices and promote inactivity (Dietz, 2004). For example, Dietz (2004) asserted "our one-on-one physician-provider relationship model is ill-suited to a problem that affects 15% of patients and engages so many environmental factors" (p. 16). Researchers suggest that pediatricians feel inadequately prepared to address childhood obesity (O'Brien, Holubkov, & Reis, 2004; Story et al., 2002; Trowbridge, Sofka, Holt, & Barlow, 2002). Physicians, as the primary provider, continue to oversee most patient care, although they are not necessarily trained to address all the complexities present with families who are seeking help for a child that is struggling with weight. Ultimately this may lead to reduced productivity, a key marker in the operational world. Therefore, the involvement of other healthcare providers becomes even more important (Dietz, 2004). Of additional importance is the operational support for financial success. Charles Homer, CEO of NICHQ states, "Having support at the top is critical, a CEO or department head who is convinced that this (childhood obesity) is a serious issue that (it) deserves extra attention and resources" (Homer, p. 37).

The operational world not only encompasses ideal training and identification of appropriate providers to tackle childhood obesity, it also includes healthcare policy. Healthcare policy is essential because policies may assist or thwart the healthcare system's ability to address obesity, specifically through multifaceted interventions (Homer & Simpson, 2007). In a report

given to the second National Childhood Obesity Congress, Simpson et al. (2008) pointed out that most policy attention in childhood obesity is focused on schools and the built environment rather than healthcare (Simpson, Alendy, Gunther Murphy, & Network, 2008). Simpson et al highlighted the particular areas of healthcare policy that should be addressed; "research and funding priorities need to identify effective prevention and treatment approaches; training and competency of healthcare professionals in preventing, identifying and treating affected children and families; inclusion of obesity-related services in benefit coverage; incentives for providers and health plans to address the issue; support of innovations, including quality improvement; and the role of health information technology (decision-support systems and obesity registries)" (2008, p. 2). Healthcare policy, productivity, and administrative tasks are also dependent upon financial feasibility.

The Financial World of Childhood Obesity

The financial world in collaboration with the clinical and operational worlds has apparent challenges. Policy leaders state that a needed healthcare system change is to "Engage payers and employers in improvement efforts, identify and address financial barriers to better care, and engage pediatric councils that work with insures on coverage and reimbursement" (NICHQ & Blue Cross Blue Shield of Massachusetts, p. 1). Homer observed "There is a long-standing and widely held belief that there are significant barriers to healthcare reimbursement. Some public (and private) plan directors have taken it upon themselves to reeducate their physicians. Even in states where there are few barriers to coverage, this belief still stands" (Homer, p. 37). Overall, physicians contend that reimbursement for obesity-related protocols and procedures are difficult to obtain.

In 2004, the United States Department of Health and Human Services removed language from the Medicare Coverage Issues Manual that indicated obesity was not an illness (US Department of Health and Human Services, 2004). This decision allowed Medicaid coverage for evidence-based obesity treatments to be developed (Rosenbaum, Wilensky, Cox, & Wright, 2005). Medicaid, covering 22.2 million children (or 28.2% of all children), is the largest single source of health insurance for children in the United States, specifically for minority children and those of low socioeconomic status (SES) (AAP, 2008; Rosenbaum et al., 2005), a group with a high prevalence of obesity. Medicaid provides coverage for children until they are 21 years old through the Early Periodic Screening Diagnosis and Testing (EPSDT) program (Wilensky et al., 2006). The EPSDT program (unlike all private insurance) focuses on early intervention, preventive care, and broad coverage; all of which are necessary for care of children who are overweight or obese (Wilensky et al., 2006).

A review conducted by George Washington University entitled *Strategies for Improving Access to Comprehensive Obesity Prevention and Treatment Services for Medicaid-Enrolled Children*, looked at how state Medicaid EPSDT programs are promoting best-practice standards in obesity related services (Wilensky et al., 2006). The researchers found that state EPSDT standards do not typically focus on obesity related activities. Additionally, Medicaid managed care contracts generally do not highlight obesity prevention and treatment strategies in reference to EPSDT standards or performance measurement requirements (Wilensky et al.). She seems to be saying that obesity programs (preventive or treatment) are not encouraged, nor are healthcare providers being held accountable for administering them.

However, “a review of state EPSDT billing, coding, and payment practices underscores that existing billing codes permit coverage to all procedures and interventions essential to high

quality obesity-preventive pediatric practice" (Wilensky et al., p. 4). Specific challenges may include limiting the number of payable/reimbursable visits, coverage based on coded services for same day visits, and operating under billing for certain overweight and obesity procedures (Wilensky et al., 2006). It appears that one common challenge in the financial world is that often providers don't know how to code for obesity and its related comorbidities (Homer, p. 37).

Wilensky et al. affirm that "Overall, Medicaid is well-equipped to tackle the rising obesity problem; the coverage is available but several obstacles exist" (p. 4). First, they recommend that states should clarify the application of obesity prevention and treatment recommendations as part of the EPSDT benefit for children and adolescents. This recommendation would "ensure that covered services are translated into best practices, state agencies could take the extra step of disseminating and ensuring use of practice guidelines then information relating to obesity-services could be included in fee-for-service guidance as well as managed care contracts." Second, clarify proper coding and payment procedures for obesity prevention and treatment services. "States could develop billing guidelines that support appropriate billing coding and could examine other payment standards and limitations that may need to be adjusted in cases involving obesity treatment and prevention (e.g., adjusting maximum visits or duration limits)" (p.5), Third, bundle obesity prevention and treatment services into a single package following a disease management model. In this model all "already-covered" Medicaid services (including behavioral health) would be bundled into an obesity prevention and treatment payment system that would include guidelines about care, instructions on billing and coding, and level of reimbursement (Wilensky et al., 2006).

Summary

The above discussion of the current status of obesity care through the three-world view (see Table 2) serves two purposes (a) to tie together the clinical, operational, and financial recommendations and research to date, and (b) to identify gaps in the literature. Evident gaps taking each world view into consideration include: 1) the lack of literature regarding communication and collaboration in the clinical world, 2) lack of policies based on best practices, and 3) lack of coordinated billing systems that reflect care-recommendations in the financial world.

Healthcare systems and obesity programs need to be adaptable to the evolving needs of overweight children and their families as more is learned about effective treatments. Pediatric obesity treatment teams, programs, and providers all could benefit from a document that bridges the disciplines of medicine and other healthcare professions (e.g., physical therapy, nutrition, behavioral health). This article serves to influence pediatric teams to include a variety of healthcare professionals to best meet the needs of our patients and their families. Behavioral health and medical experts alike can benefit from a collaborative and integrated team dynamic that brings together multiple players from diverse areas of medical and behavioral health expertise, in order to treat a complex chronic illness such as obesity. Recommendations based on the clinical, operational, and financial worlds as they pertain to the four stages of treatment are offered below. These recommendations are intended for providers, researchers, policy makers, and payers in order to maximize the synergy of the three-world view in pediatric obesity treatment.

Recommendations

In the clinical world, providers should employ family-centered care for all stages of obesity treatment (i.e., prevention plus to tertiary care). Services should be coordinated between the primary care physician (i.e., pediatrician) and other referrals, as is recommended for structured weight management, comprehensive multidisciplinary intervention, and tertiary care intervention. Multidisciplinary care should be considered at the first stage in a prevention plus encounter. In addition to the preventive practices conducted with the physician, healthcare professionals specializing in nutrition, exercise, and behavior change could consult with the primary care provider for those children with borderline weights. Optimally, anytime a referral is made or communication takes place between providers, that (a) coordination of services is arranged, (b) collaboration between the healthcare providers and family members is maximized, (c) the policies and procedures present in the system supports collaboration, and (d) multidisciplinary obesity-related billable services are coordinated.

In a tertiary care setting, with children at the highest risk of complications of being overweight integrated care maybe the type of collaboration that is best suited to accomplish weight maintenance or loss. The involvement of behavioral health professionals integrated within collaborative care allows the focus on “weight” to shift to a more overall “health related quality of life” emphasis, while additionally paying attention to psychosocial issues that may make weight loss challenging (e.g., parent divorce, a death in the family, depression). Larger studies confirm that behavioral skills and approaches are essential to understanding what factors are associated with patient success. Thus, providers with behavioral medicine/psychology weight management expertise must be included in treatment teams (Whitlock et al., 2008).

The operational world should be able to adjust to the multiple disciplines present in the clinical world. Office staff and support will need to adjust for new providers who may be scheduling new patients and requesting other administrative services, such as new encounter forms or record keeping systems. The importance of having record keeping systems with the capability of managing diverse services by multiple providers concurrently is optimal for integrated and collaborative care. In addition, providers need to be able to share records and detail assessment, diagnoses, and treatment easily if not within the same physical document. In order to determine productivity of various collaborative care models (i.e., integrated care) the operational world must capture the number of patients being seen "individually" with each provider, as well as the number of integrated care or collaborative care encounters. In order to explore, analyze, and implement policies and procedures that maximize productivity outcomes, treatment and financial feasibility should be measured via the unique treatment modalities (e.g., traditional vs. integrated care).

In addition to direct care procedures with patients, the operational world also must capture the operations of the work environment. Therefore, treatment teams should hold regular meetings to discuss clinical operations. Larger team meetings should also involve individuals that are part of the administrative and financial staff, thereby maximizing collaborative policies that then influence the clinical and financial worlds.

The most important issue with regard to the financial world is adjustments that must be made in order to provide multiple billable services with a variety of healthcare professionals (e.g., physician, nutritionist, behavioral health specialist, and exercise physiologist) that are part of a same-day encounter. Because the comorbidities associated with childhood obesity are both biological and psychosocial, services should be reimbursable for treatment interventions from

medical providers and behavioral health professionals. A concern that connects all three worlds is the lack of reimbursement for necessary childhood obesity treatment (e.g., preventive counseling, multiple provider encounters within the same day or visit, and only a certain number of reimbursable sessions with a behavioral health specialist or nutritionist). On the other hand, many who need treatment may not be able to afford the services, so attention must be given to patients from diverse socioeconomic status and those that may have barriers to treatment (e.g., proximity from treatment centers).

Childhood obesity has become an epidemic; one that cannot be treated in isolation. The clinical, operational, and financial strengths and challenges must be explored and analyzed through collaborative and multidisciplinary/integrated teams who can offer practices and procedures that maximize health outcomes, provider productivity, and financial feasibility. Integrated care is only one component of childhood obesity treatment and without the synthesis of the operational and financial worlds will not succeed. Without such practices obesity treatment will continue to be suboptimal and more families will have their lives and health impacted by obesity.

Table 1: Important Terms

Term	Definition	Example
Behavioral Health	Serves as an overarching term encompassing "mental health", "substance abuse", and "behavioral medicine." (Blount et al., 2007)	An individual working with an obese child who is trained in behavioral health may be a family therapist, psychologist, psychiatrist, social worker, or case manager.
Behavioral Medicine	Services designed to intervene on physical health using behavioral means. (Blount et al., 2007)	Behavioral medicine services may include but are not limited to health behavior change programs, education for coping with illness, programs to improve adherence to medical regiments, and services that access the relaxation response (e.g., relaxation training, biofeedback, mindfulness).
Collaborative Care	A team with at least one medical provider and one behavioral health provider. Collaboration is an understanding that improvements in patient care are achieved more efficiently by working together and focusing on systems than they would be by working independently and focusing on individuals. (Blount et al., 2007; Kilo, 1999).	A physician, nutritionist, and behavioral health professional all view a patient and his or her family as the focus of treatment. There is shared communication around treatment goals and progress.
Co-located Services	Places multiple services in the same physical space in hopes that close proximity will enhance the outcome of services for a population. Co-location goes beyond sharing the same physical space to include the same office staff and waiting facilities (Blount et al., 2007; Ginsburg, 2008)	For example, a pediatrician and nutritionist may share the same secretarial support, nursing/laboratory services, as well as examination rooms. *It is possible for services to be co-located and not coordinated, and may be integrated and not co-located (Blount, 2003).
Coordinated Services	Coordinated care can range from informal to formal depending on the level of patient care and communication among providers. Healthcare providers that jointly review cases, treatment plans, or needed referrals are coordinating care. (Ginsburg, 2008)	A physician that communicates with a nutritionist regarding a patient's treatment plan is coordinating care.
Family-centered Care	Based on the understanding that the family is the child's primary source of strength and support and that the child and family's perspective and information are important in clinical decision making. It is an approach to prevention, assessment, and treatment that considers not only the child as the identified patient but the family that the child is in consistent contact with. (Pediatrics, 2007)	A family-centered weight loss program includes praising the child's healthy behavior choices, not disciplining with food (e.g., no rewards), providing structured feeding times, deciding what healthy options are offered, removing temptations from the child's environment, parental modeling of health behaviors, and providing all of the above consistently in the home (Barlow & Dietz, 1998).
Integrated Care	Integrated care is collaborative care that addresses the biopsychosocial symptoms of patients. Care is highly coordinated between medical and mental health providers, which can be seen through shared treatment plans (Patterson et al., 2002). What separates integrated care from collaborative care is the appearance of the "unified provider." Integrated care involves at least one medical and behavioral health	Often in an integrated care setting a medical and behavioral health provider will provide side-by-side services for a patient (Patterson et al., 2002). Integrated care may involve more than a medical and behavioral health provider; as is the case with childhood obesity where often a physical therapist, case manager, and nutritionist or dietician is included as well. In an integrated care consult a physician and behavioral health

	provider incorporated into a patient's treatment plan. (Blount, 2003)	professionals may see a patient together in the same physical space at the same time.
Multidisciplinary Care	Includes the expertise of several different disciplines (e.g., medical, nutrition, endocrine, family therapy, exercise physiology).	For example an overweight child may see a nutritionist, pediatrician, and exercise physiologist, possibly at different appointments or settings.

Table 2: Summary of the Expert Recommendations and the Three-world View at the Recommended Stages of Obesity Treatment.

	Clinical World	Operational World	Financial World
Stage 1: Prevention Plus	• Family Centered • Referrals for outside care if necessary (e.g. nutrition)	• Primary provider (e.g. physician) administrative support in scheduling for one primary provider's patients • Information for referrals offsite	• Reimbursable medical procedures as done by a physician
Stage 2: Structured Weight Management	• Family Centered • Multidisciplinary with an added healthcare professional with childhood obesity expertise (typically a nutritionist at this stage) • Coordinated Care for offsite referrals *no detail about collaboration with the added healthcare professional	• Provider (e.g. physician and nutritionist) administrative support with scheduling and for additional providers • Information sharing and releases *no detail about how to scheduling or administrative support for the added healthcare professional	• Reimbursable medical procedures as done by a physician *no detail about how to reimburse for the added healthcare professional
Stage 3: Multidisciplinary Intervention	• Family Centered • Multidisciplinary with the addition of behavioral treatment • Coordinated Care of services either on or offsite *No detail on communication with or collaboration with the added healthcare professionals (e.g. shared treatment planning and goals)	• Multiple provider administrative support • Information sharing and releases • Shared nursing staff and medical facilities • Shared treatment plans *No detail about how administrative support facilitates multiple providers (e.g. scheduling, nursing services, etc)	• Reimbursable medical procedures as done by the physician *No detail about how to reimburse for multiple providers in the same physical setting on the same day.
Stage 4: Tertiary Care Intervention	• Family Centered • Multidisciplinary with Behavioral Treatment • Coordinated Care	• Providers administrative support • Information sharing and releases • Shared nursing staff and medical facilities • Treatment team meetings *No detail about how administrative support	• Reimbursement for higher level services • Bundled services

	*No detail about collaborative or integrated care treatment team facilitation (team meetings, patient flow, and shared treatment planning).	facilities multiple providers (e.g. scheduling, nursing services, etc).	*No detail about how to reimburse for multiple providers in the same physical setting on the same day.

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Abstract

BIOPSYCHOSOCIAL CHANGES IN CHILDREN AND CAREGIVERS PARTICIPATING IN AN INTEGRATED PEDIATRIC OBESITY TREATMENT PROGRAM

by

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March 3, 2010

Chair: Angela L. Lamson, Ph.D.

Major Department: Child Development and Family Relations

The purpose of this manuscript is to explore: 1) biopsychosocial healthcare outcomes for the Pediatric Healthy Weight Research and Treatment Center patients and families who receive a stage three, integrated care treatment model for childhood obesity treatment and 2) changes from patient and caregiver baseline variables in quality of life (QOL), depression level, and child health status variables (i.e., Body Mass Index [BMI], weight, and BMI z-score) across three different visits. At their initial visit (V1) a sample of 267 pairs of child and caregiver participants was recruited from East Carolina University's Pediatric Healthy Weight Research and Treatment Center (PHWRTC) in Greenville, NC; of the 267, 113 attended a visit two (V2) follow-up appointment, and 48 attended visit three (V3). Paired t-tests, analyses of variance, correlations, regression, and chi-square cross-tabulations were conducted to determine baseline variables, relationships at baseline, changes in variables and relationships over time, and predictors of patient attrition. Overall across three visits (V1-V2-V3) the results indicated that children declined in relative BMI, significantly increased their QOL, and improved their depression level. Similarly, caregivers' perception of their child's QOL increased and teen's

depression level improved across three visits. Our results indicated that we cannot neglect the psychosocial impact that multidisciplinary integrated treatment teams can have on families. In accordance with the *Expert Recommendations*, we believe a family-centered approach is the best way for clinicians to address obesity in children, however we contend that if a center has the appropriate staffing, that family factors such as parental depression should be addressed as well. In addition to assessing for depression and quality of life, we believe more relational assessments are important in order to see how obesity manifests in families; such as family conflict, parenting style, and stress.

Biopsychosocial Changes in Children and Caregivers Participating in an Integrated Pediatric Obesity Treatment Program

A Dissertation Presented to

the faculty of the Department of Child Development and Family Relations

East Carolina University

In Partial Fulfillment of the

Requirements for the Degree Doctor of

Philosophy in Medical Family Therapy

by Keeley J. Pratt, MS, Doctoral Candidate

March 3, 2010

Introduction

Today, childhood obesity is identified as a nationwide epidemic that impacts children regardless of sex, age, race, and ethnic group (Federal Interagency Forum on Child and Family Statistics, 2007; Hedley et al., 2004; Institute of Medicine, 2005). According to the 2003-2004 National Health and Nutrition Examination Survey (NHANES), 17% of children and adolescents aged 2-19 are overweight (US Department of Health and Human Services, 2005). From 1994 to 2003, the rate of overweight in adolescents aged 12-19 increased from 11% to 17% (US Department of Health and Human Services, 2005).

This epidemic has led clinicians and researchers to come together to formally develop a set of guidelines for treating this condition in children and families. The report, entitled *Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity* (2007), summarizes the findings of the currently accepted practices for pediatric obesity prevention, assessment, intervention, and treatment (Barlow, 2007). This report synthesizes several elements that have previously been neglected from obesity treatment recommendations, such as family involvement, inclusion of multidisciplinary providers, and specific trajectories of treatment for children who are at an unhealthy weight. At present, this is the most comprehensive document in existence for all healthcare providers, regardless of their discipline, to utilize in the battle against the obesity epidemic.

The report details four stages of childhood obesity treatment: 1) prevention plus; 2) structured weight management; 3) comprehensive, multidisciplinary intervention, and 4) tertiary care intervention (Barlow, 2007). The participants for our research were drawn from the Pediatric Healthy Weight Research and Treatment Center (PHWRTC) in Greenville, North

Carolina. The PHWRTC employs a stage three treatment strategy (Barlow, 2007); which is defined as a comprehensive multidisciplinary intervention that goes beyond stage two, by utilizing multidisciplinary childhood obesity treatment and a structured behavioral program (e.g., negotiating and reinforcing positive healthy behaviors). Families are seen weekly for 8-12 weeks with additional follow-up services. At the PHWRTC, children are ideally seen every month (rather than every week as recommended by the *Expert Recommendations* for children who have complications from their overweight); however, the rural population, low income, and poor access to transportation thwart a strong show rate.

In addition to employing a stage three treatment strategy (Barlow, 2007), the PHWRTC uses an integrated care model, which is an intense form of collaborative multidisciplinary care. Care is highly coordinated between medical and mental health providers, which can be seen through shared treatment plans (Patterson et al., 2002). Often in an integrated care setting, a medical and behavioral health provider will provide side-by-side services for a patient (Patterson et al., 2002). In the case of the PHWRTC, a pediatrician, marriage and family therapist/medical family therapist, and licensed dietician are included in the treatment model. Integrated care models, including family-centered and behavioral treatments, when followed longitudinally will give a more accurate picture of what is happening biologically, psychologically, and socially for patients who are overweight and their families.

The biopsychosocial (BPS) approach, developed by George Engel in 1977, explores health as an interplay of biological, psychological, and social systems (Engel, 1977). For example, being overweight or obese has several physical implications (e.g., trouble sleeping) that might also be complicated by psychological symptoms (e.g., depression) or social concerns (e.g., being bullied). In order to seek out longitudinal changes through integrated care treatment, we

developed a protocol for assessing BPS indicators for overweight or obese children and caregivers.

Our purpose is twofold, 1) we are curious about BPS healthcare outcomes for the PHWRTC patients and families who receive a stage three, integrated care treatment model for childhood obesity treatment and 2) we are interested in the changes from patient and caregiver baseline variables in quality of life (QOL), caregiver and teen depression level, and child/teen health status variables (i.e., Body Mass Index [BMI], and BMI z-score) across three different visits to our clinic. We hope to add to other research efforts attempting to generate a comprehensive and longitudinal picture of how obesity is affecting children and their caregivers. Finally, we wish to add to the current childhood obesity treatment protocols by expanding standard biomedical assessments to include psychosocial inventories.

Literature Review

Childhood obesity researchers have documented QOL, depression, and health status variables in multiple studies utilizing different methodologies and research designs; while some researchers have found that contextual variables tend to be correlated with higher rates of obesity including age (as it relates to ethnicity), socioeconomic status (SES), and parental constellation (e.g., single parent or two parent) (Golan, Fainaru, & Weizman, 1998; IOM, 2005; DHHS HRSA MCHB, 2005). Many variables and populations remain under-researched (e.g., those of diverse ethnicity, SES, and parental constellation) with a lack of consistency in treatment outcomes with regard to overweight children and their families.

Ethnicity & Age

Nationally, the prevalence of childhood obesity is most significant in middle-and high school-aged children and those from ethnic minority populations (e.g., African American and

Mexican American) (Hedley et al., 2004; Ogden, Carroll, & Flegal, 2002, 2008). According to National Health and Nutrition Examination Survey (NHANES) data, non-Hispanic black children have the highest rate of obesity (22.9%), with Mexican American and non-Hispanic white children at a lower prevalence (comparatively), at 21.1% and 16% (DHHS HRSA MCHB, 2005; Freedman, Dhan, Serdula, Ogden, & Dietz, 2006; Hedley et al., 2004; Ogden, Carroll, & Flegal, 2002, 2008). Asian children appear to have similar obesity prevalence as white children (Freedman et al., 2008). Specifically, child populations that have the highest prevalence of obesity include adolescent Mexican American boys (22%) and non-Hispanic black girls (24%) (Caprio et al., 2008). These differences may be due to multiple complex variables interacting with ethnicity, sex, and SES.

Socioeconomic Status

The assessment of SES is often comprised of systemic variables such as family income, caregiver education, and residential proximity. All of these variables appear to be associated with the prevalence of childhood obesity. For instance, family income has been shown to have an inverse relationship with childhood obesity; as income increased, the prevalence of obesity in children decreased (DHHS HRSA MCHB, 2005). While current estimates reveal that almost half of U.S. adult obesity-attributable medical costs are funded by Medicaid or Medicare (Finkelstein, Fiebelkorn, & Wang, 2004), costs to insurers for children is inconsistent with some reports stating there is not an increase in healthcare costs (Simpson & Cooper, 2009).

Family Structure

In the National Survey of Children's Health (2003-2004), parental/family structure (e.g., single parent or blended families) was found to be one factor that influenced overweight or obesity in children. For example, children who lived in two parent (biological or adoptive)

households were least likely to be overweight (12.2 %) as compared with children who lived with at least one step parent (15.2 %); children who lived with single mothers (18.9 %) had the greatest prevalence of overweight (DHHS HRSA MCHB, 2005). Researchers have yet to document why single mothers are more likely to have children who are overweight than those in dual parent homes. Additionally, obese or overweight adolescents who did not live in two parent homes were more likely to be depressed, have lower self-esteem, and have poorer school functioning (Swallen et al., 2005). While analyzing family/parental structures is important in order to generate a comprehensive picture of childhood obesity, it is also essential to discuss biological, psychological, and social symptoms that overweight children and their caregivers may be experiencing.

Biopsychosocial Approach

Biological

The medical literature has documented multiple biological comorbidities of childhood obesity including endocrine problems, heart disease, high cholesterol, hypertension, early puberty, and enuresis (Dietz, 1998; Kiess et al., 2001, IOM, 2005; DHHS HRSA MCHB, 2005). Other comorbidities associated with obesity include obstructive sleep apnea, metabolic syndrome, acanthosis nigricans, polycystic ovarian syndrome, and type 2 diabetes (Hassink, 2007). To further complicate matters, children and families are expected to meet with multiple providers and follow treatment plans based on disconcerting results from sleep studies, fasting glucose levels, cholesterol and triglyceride tests, and perhaps most importantly family medical history. Body Mass Index (BMI) can also be complex for families to understand, especially since it is interpreted different for adults and children.

Psychological

There is little current research documenting the psychiatric and psychological problems in children or their families seeking treatment for obesity. Epstein, Valoski, Wing, and McCurley (1994) completed a ten-year follow-up study of family-centered treatment for childhood obesity and found the most prevalent psychiatric problem is depression (Epstein et al., 1994). In a sample of obese children entering treatment, it was found that 29% met or exceeded clinical levels for psychosocial problems on the Child Behavior Checklist (Achenback, 1991), specifically anxiety and depression. In another sample of obese adolescents presenting for bariatric surgery, 30% met criteria for clinically significant depressive symptoms (Zeller et al., 2006). As previously stated, the effect of treating specific familial psychological issues such as depression and low self-esteem over time in conjunction with behavioral lifestyle interventions is lacking in the literature.

Researchers indicate that children who are obese have increased likelihood for psychological problems that may persist into adulthood as compared to children who are not obese (Epstein, Paluch, Gordy, Saelens, & Ernst, 2000). Psychological impairments include poor self-esteem, low self-worth, depression (IOM, 2005; Speiser et al., 2005), loneliness, poor self image, suicide, drug and alcohol addiction, bulimia, binge eating, and smoking (DHHS HRSA MCHB, 2005; Hoot & Lynn-Garbe, 2005; Kiess et al., 2001).

Social

According to Edmunds and colleagues (2001) the social implications for children who are overweight are evident in children as young as six years of age, when children begin to understand societal messages that being overweight is not desirable (Edmunds, Waters, & Elliott, 2001). Not surprisingly, children who are overweight are more likely to be at risk for peer

victimization such as teasing or bullying (Griffiths, Wolke, Page, Horwood, & Team, 2006; Janssen, Craig, Boyce, & Pickett, 2004; Latner, & Stunkard, 2003). Additional social issues for children who are obese include problems associated with school (e.g., performance or school attendance), relational issues (e.g., with family and friends), social isolation, and promiscuity, Peer perceptions of children who are obese includes characteristics such as selfishness, poor academic success, and lower intelligence (Epstein, Roemmich, & Raynor, 2001). Given the literature above, the BPS symptomatology and comorbidities accompanying childhood obesity warrant new treatment modalities that include a multidisciplinary and biopsychosocial approach.

BPS & Quality of Life

A formal assessment of quality of life is one method to comprehensively assess how weight may impact a child from a BPS approach. Numerous researchers have used quality of life (QOL) inventories, particularly the PedsQL4.0© (Chan, Mangione-Smith, Burwinkle, Rosen, & Varni, 2005; Varni, 1999, 2001, 2002, 2003). The PedsQL inventory is used to assess physical, emotional, social, and school functioning, thus providing physical and psychosocial outcomes all in one tool. The domains measured by the PedsQL inventory appear to be comparable to the systems described in Engel's BPS model (Engel, 1977); the biological system relates to the physical domain, the psychological system to the emotional domain, and the social system to the social and school domains.

Investigations of the relationship between weight and QOL in children have produced inconsistent findings. For example, some researchers have concluded that there is not an impaired QOL for children at an increased weight (Janicke, 2007). However, other researchers have found a relationship between being overweight and decreased QOL in children and adolescents (Ravens-Sieberer, Redegeld, & Bullinger, 2001; Schwimmer, Burwinkle, & Varni,

2003; Swallen, Reither, Haas, & Meier, 2005). Schwimmer et al. (2003) found that obese children are 5.5 times more likely than healthy children to have impaired QOL, making QOL for an obese child similar to that of a child diagnosed with cancer (Schwimmer et al., 2003). Quality of life appears to be inversely related to weight; as a child's weight increases, her QOL decreases, so the most overweight children have the most significantly impaired QOL (Williams, Wake, Hesketh, Maher, & Waters, 2005; Zeller, Roehrig, Modi, Daniels, & Inge, 2006). Due to the lack of longitudinal data, it is unclear whether specific psychological issues (e.g., depression and/or anxiety) persist from youth to adulthood and how they influence QOL over time.

Some researchers have contended that contextual variables (as previously described) further complicate QOL as it pertains to obesity. Ogden et al. (2002) indicated that sex and race play a significant role in quality of life for overweight and obese adolescents. In regard to sex differences and QOL, overweight or obese boys report higher physical functioning (Janicke, 2007), while girls report lower social functioning (Zeller et al., 2006). Furthermore, race, specifically being Black, was associated with low QOL scores with African American obese girls. Overall, across all races surveyed, impairments in physical functioning are more frequently reported than those of emotional, social, or school functioning (Pinhas-Hamiel et al., 2006; Swallen et al., 2005).

Caregiver-related Variables

Maternal Depression

Maternal depression is commonly associated with less reactive, more withdrawn, and emotionally negative behavior toward the child(ren) (Lovejoy, Graczyk, & O'Hare, 2000). Maternal depression may be of particular interest when children are trying to change physical activity and dietary behaviors and could benefit from support from their caregivers via behavior

changes (e.g., not using food to discipline or as a reward) (Pott, Albayrak, Hebebrand, & Pauli-Pott, 2009). Researchers have documented inconsistent findings when looking at the relationship of maternal depression and children's weight. Some researchers have found no significant association between childhood obesity and maternal depression (Pott et al., 2009). Other researchers have found a trend for the mothers of treatment-seeking children to report higher levels of depression than the mothers of equal weight non-treatment seeking children (Gibson et al., 2007). The unclear picture of caregiver-related variables, including maternal depression level, has prompted clinicians to assess for readiness to change new health behaviors, not only for children, but also for caregivers in order to remain family-centered in their treatment planning.

In order to explore healthcare outcomes for children and their families at the PHWRTC who are receiving stage three-integrated care; we chose to measure our multidisciplinary team intervention utilizing multifaceted BPS constructs. Using a multidisciplinary team mandates outcome variables that are not restricted to isolated measures of weight-loss, but also include measures of overall well-being (i.e., QOL). We chose to explore the BPS constructs of QOL, depression level, and measures of BMI (and other health status variables) for children and caregivers from baseline through two follow-up visits. In order to align with the *Expert Recommendations*, we wanted to have measures of well-being for the children and the caregivers seen at the PHWRTC.

Research Questions

1. What are the baseline characteristics of the children and their caregivers in terms of age, race, sex, caregiver relationship to the children, QOL total and scale scores, depression

levels of child (teen) and caregiver, and child/teen health status (including BMI z-score, weight, BMI, and BMI category).

2. At baseline, what are the relationships between (a) QOL and relative BMI; (b) QOL and PHQ-9 scores; and (c) BMI category/relative BMI and PHQ-9 scores and are these relationships related to the child's/teen's age, sex, or race?
3. Are there changes in QOL, relative BMI, and PHQ-9 from V1 (initial visit) to V2 (first follow-up visit) to V3 (second follow-up visit) for the total group?
4. Are the V1 – V2, and V1 – V2 – V3 changes in QOL, relative BMI, and PHQ-9 related to (a) child's/teen's race; (b) time between visits; or (c) sex of the child/teen?

Method

Description of the Center

The PHWRTC located in Greenville, NC, is committed to the prevention and treatment of childhood obesity by including the family, school systems, pediatricians, dieticians, and family therapists as a part of the child's overall care. The mission of the PHWRTC is to reduce childhood obesity in eastern North Carolina, through collaboration with local health care providers and community agencies, and through the development, application, and dissemination of translational basic science and clinical research in both community and academic settings. Our sample was drawn from the PHWRTC Pediatric Specialty Unit (procedure described below). Child participants are referred to the PHWRTC for clinical services from their primary care physician because of a concern about the child's weight and the risk of weight-related comorbidities. The PHWRTC serves families primarily from rural eastern North Carolina. Children and their caregiver(s) who are seen at the PHWRTC are diverse in their race, socioeconomic status (SES), and sex. Of the general population seen at the PHWRTC, 70%

receive Medicaid or Health Choice insurance and 63% are African American. Health Choice insurance is for families who make too much money to qualify for Medicaid, but too little money to afford health insurance premiums.

The PHWRTC is one of several clinics housed in the ECU Pediatric Specialty Unit. Providers include three different physicians that rotate clinical time, one registered dietitian and licensed nutritionist, one doctoral level medical family therapist, and one master's level family therapy intern. The PHWRTC is open two days a week with four time slots available on each given day for initial visits, and seven time slots for follow-up visits (which are often shorter in length).

At the initial visit to the PHWRTC, patients and their caregivers will meet with several providers from different disciplines throughout the day. All providers (pediatrician, nutritionist, and family therapist) work from an integrated care model where care is shared among all providers with a high level of collaboration before, during, and after visits. Treatment plans are grounded in BPS constructs and are formulated with each team member's involvement as well as the families', thereby establishing the Clinic as a stage three or comprehensive multidisciplinary intervention.

Regular follow up appointments are scheduled, typically at least every three months and are shorter in duration. Height, weight, BMI and blood pressure are tracked by the nursing staff, and BMI percentile is plotted by the medical provider at each visit. Physical activity behaviors are tracked by the pediatrician at each visit and QOL and depression are tracked by the family therapist.

Study Design and Sample

A longitudinal panel descriptive design is used for this study. This design allows for the investigation of multiple factors experienced by children who are overweight and their caregivers across up to three different integrated care visits (V1, V2, and V3). Patients who are excluded from the research include children under the age of eight, those who are wards of the state or live in a foster home environment, those who are cognitively impaired (as identified by the electronic medical record or provider's evaluations), or do not speak English. Following the approval of the East Carolina University institutional review board (see appendix A), investigators began recruiting participants for the study.

Procedure

The research opportunity was presented to children ages 8-18 and their caregiver(s) at the child participant's initial visit to the PHWRTC. All participants were notified that clinical services are not contingent upon research involvement. At every visit subsequent to the initial, the research packet was re-administered with the same measures, excluding the family characteristic questionnaire. The child research packet contained the age appropriate PedsQL4.0 and PHQ-9 assessments for children ages 8-18. For children under 13 years of age, depression is assessed via the emotional and social domains of the PedsQL. The primary investigator or a member of the research team makes a notation regarding which caregiver fills out the research packet at each visit. If questions arise while the child or caregiver(s) is taking the survey, a member of the research team is available to provide clarity or answer questions. A member of the research team is available to assist children who have trouble reading, by reading aloud the questions and circling the corresponding answer that the child selects.

Upon completion of the research packets, the principal investigator (PI) or the family therapy intern scores the measures immediately for clinical relevance. Results are discussed with the patient at the end of the visit with the physician present. It is important to note that these measures are used for research and for clinical purposes in order to promote discussions about biopsychosocial indicators at post-visits with children and caregivers.

Immediately following the patient's check-in and consent for treatment, the family is given an introduction/agenda for the day by the physician. First children have their blood work done in the PHWRTC lab. Blood work typically includes cholesterol, blood sugar, leptin, etc. In addition, children over age seven do an indirect calorimetry which gives them their resting expenditure rate and approximates their ideal daily caloric intake. Height and weight are then measured in order to calculate and plot BMI (on age and gender appropriate charts) and followed by a check of blood pressure.

The family therapist then greets the patient and family to assess for quality of life, and depression (via the PedsQL4.0 and PHQ-9, respectively), and presents the research opportunity for those eligible patients. Following these measurements, patients receive a comprehensive integrated care BPS evaluation from general pediatrician, pediatric dietitian, and family therapist, all with a special interest and training in obesity. Patients will meet with the pediatrician for a medical history (i.e. number of hospitalizations, concerns related to weight of other family members) and physical exam. The family therapist intern is present during the medical history interview, providing psychosocial expertise when appropriate. The family therapist will also speak with the family after the medical encounter to address any relevant psychosocial issues. After the visit with the physician and family therapist, the patient will meet with the nutritionist

and develop goals related to nutrition. Children who already have noted joint complications are referred for physical therapy off-site.

At subsequent visits, children and their caregivers are asked again to fill out the research packets. After data collection is complete, child and caregiver scores are entered into a statistical database (SPSS version 16) by the PI. The research packets are stored under double lock and key. Child participants' medical charts are retrieved by the PI in order to extract date of birth, height, weight, and Body Mass Index (BMI).

Measures: Outcome Variables

Pediatric Quality of Life Inventory 4.0

The PedsQL4.0 is used as an overall biopsychosocial healthcare assessment for PHWRTC patients and their caregivers. This tool addresses the biological system via the physical dimension, psychological system via the emotional dimension, and social system via the social and school dimensions. The PedsQL4.0 is cited in numerous publications on childhood obesity attesting to its value (Chan, Mangione-Smith, Burwinkle, Rosen, & Varni, 2005; Varni, 1999, 2001, 2002, 2003). Schwimmer, Burwinkle, and Varni (2003) found that the total scale score for both the child and caregiver reports have demonstrated at least a Cronbach α reliability coefficient of .90, and thus can be utilized for individual patient analysis and as a health related quality of life outcome measure for clinical trials. Our sample yielded reliability coefficients of .89 and .92 for the PedsQL child and caregiver, respectively. This measure is also recognized for the age appropriateness for children (ages 5 to 18) and parallel caregiver module that is also available. There are different age appropriate module levels for children to complete: young child (5-7 years old), child (8-12 years old), and teen (13-18 years old).

All three PedsQL4.0 modules consist of 23 items. The 23 items are broken down into four dimensions: physical functioning, emotional functioning, social functioning, and school functioning. Items are ranked on a reverse-likert scale ranging from (0) never a problem, (1) almost never a problem, (2) sometimes a problem, (3) often a problem, to (4) almost always a problem. The following outcome variables were used for the PedsQL: child total score, caregiver total score, child subscale (physical, emotional, social and school) scores, and caregiver subscale scores.

The biological context (of the BPS approach), as measured by the PedsQL, encompasses overweight children's physical functioning. Specifically, the assessment of physical functioning includes assessment of body aches, low energy, hygiene, walking, running, and sports or activity. Physically, the QOL assessment helps the researcher to identify overall physically functioning in overweight or obese children.

The psychological context (of the BPS approach), as measured by the PedsQL, encompasses overweight children's emotional functioning. Emotions that are assessed include feeling afraid, sad, worried, and angry. Psychologically, the QOL assessment helps the researcher to assess overall emotional functioning that may be impacting multiple health-related areas of a child's life such as emotional eating or how these concerns may be impacting a child's social world.

The social context (of the BPS approach), as measured by the PedsQL, encompasses overweight children's functioning in relationships with their friends, families, and peers at school. In addition, the social area includes bullying, teasing, and social isolation. Socially, the QOL assessment helps the researcher to identify child and caregiver risks, as well as

discrepancies between child and caregiver interpretations (e.g., incongruence between child and caregiver perceptions on child's physical, emotional, social, and school functioning).

Patient Healthcare Questionnaire

The Patient Healthcare Questionnaire (PHQ-9) (Pfizer, 2000) assesses depressive symptoms experienced throughout the two-week time frame prior to completing the measure. The PHQ-9 consists of nine questions, with responses ranging from: not at all (0), several days (1), more than half the days (2), and nearly every day (3). The result from the PHQ-9 is a depression severity score, ranging from no depression (0-4), mild depression (5-9), moderate depression (10-14), moderately severe depression (15-19), and severe depression (20-27). This measure is used to assess for depression and suicidal ideation in caregivers and overweight children (≥13) seen at the PHWRTC. Kroenke, Spitzer, and Williams (2001) reviewed their earlier studies on the PHQ-9 (Spitzer et al., 1999, 2000) and reported a Cronbach's α of 0.89 in internal reliability as well as an excellent test-retest reliability. For our sample, the PHQ-9 reliability coefficients were .78 and .84 for child and caregiver, respectively. The PHQ-9 is appropriate for individuals aged 13 and older to complete. In addition, the PHQ-9 is administered to caregivers to explore their depressive symptoms and psychosocial status.

Measures: Predictor Variables

Relative BMI

In addition to the previously mentioned assessments, we request biological and physiological indicators from patients to evaluate health status variables. BMI is a common health indicator used for children who are overweight or obese. However, because children are growing in height, "relative BMI" that takes into account age and gender is more sensitive in tracking longitudinal changes. In our study we used two measures of relative BMI: BMI z-score

(the LMS method) and percent overBMI. The LMS method converts a regular BMI measure to a normally distributed standard deviation, also known as a z-score (Cole, Bellizzi, Flegal, & Dietz, 2000). BMI z-score is most helpful in identifying where an individual is relative to the population norm (Paluch, Epstein, & Roemmich, 2007). One challenge with BMI z-score, is the potential for the z-score to attenuate change for heavier children, hence if children become more overweight they show less change and the variability in their response to treatment is reduced (Cole, Faith, Pietrobelli, & Heo, 2005). However, percent overBMI looks at the percent above the 50^{th} percentile (on BMI), taking into account age and gender (Paluch et al., 2007). Percent overBMI gives you a value that is either positive or negative; positive values are over the 50^{th} percentile and negative values are under (Paluch et al., 2007). In comparing three different methods of relative BMI (two being BMI z-score and percent overBMI), Paluch et al. found that percent overBMI was the most sensitive in response to heavier children with a larger relative BMI change, and concluded percent over BMI is most beneficial to use in studies evaluating predictors of change (using baseline variables). In order to determine the BMI percentile for our sample, we used CDC growth charts for boys and girls of each age (CDC, 2000, 2005). We used the three categories: overweight, obese, and severely obese. Overweight was defined as those between the $85\text{-}95^{th}$ percentile, obese 95-99, and severely obese ≥ 99.

Time between Visits

Because of the variability in time between patient visits, QOL, PHQ-9, and relative BMI differences were adjusted to reflect score changes per month (using 30 days as the base). For example, if a child had a 10 point increase in QOL from V1 – V2 and the time between visits was 30 days, then the QOL change would be 10 points per month. If another child had a 10 point increase in QOL from V1 – V2 and the time between visits was 60 days, then the per month

increase in QOL would be 5 points. In the tables and results the mean differences adjusted for time between visits is called adjusted mean difference and abbreviated “Adj. Mean Dif.”. In the results and tables time between visits was called adjusted time or abbreviated as “Adj. Mean Dif.”

Sociodemographic Variables

A demographic questionnaire is administered at the initial visit to the child’s caregiver. This questionnaire includes items such as race, age, sex, educational level, occupation, income, family structure, who lives in the household, and the age at which concerns arouse in regard to child’s weight (see Appendix C). This questionnaire assists researchers in determining potential variables that could affect the family and child.

Sociodemographic variables that are included in our analysis include: child age, child sex, child race, caregiver age, caregiver sex, caregiver race, caregiver age, family structure, caregiver education level, and caregiver job status. Child age was categorized into two groups: 8-12 and 13-18 years of age. Race was categorized into three groups: black, white, and other. Only, 6.7% of our sample was not black or white. Family structure was categorized into four groups: two parents, single parent, step-family, and other. Parental education was categorized into grammar school, some high school (less than 11 years), high school graduate, some college, college graduate, associate’s degree, and graduate school. Our measure of household income was based on the form of child insurance categorized as: traditional, Medicaid, Children’s Health Insurance Plan (CHIP), and other.

Statistical Analysis

SPSS for Windows, version 16.0, was used to manage data and run all analyses. The first part of our analysis strategy included checking all variables for missing data, entry errors,

skewness, and outliers. Descriptive statistics were run on all variables. Cronbach's α was used to estimate the internal-consistency reliability of the PedsQL and PHQ-9 inventories (see above scale-specific reliability coefficients). Associations between categorical variables were analyzed using a chi-square test for independence. One-way ANOVA was used to compare means between independent groups, and a paired-t test to compare within-group mean differences between visits. Correlations were used to investigate relationships between continuous variables. We used Cohen's (1988) guidelines for interpreting the strength of the correlations. Correlations <.30 (less than 9% shared variance) represent small correlations, correlations between .30 - .49 (9% to <25% shared variance) are designated medium correlations, and correlations .50 – 1.00 (25% - 100% shared variance) are designated large correlations. We evaluated statistical significance with a p-value <.05.

Results

We organized our results based on the order of the research questions above. The first set of results describes baseline and longitudinal demographics. The second set of results describes baseline relationships at visit one (V1). The third set of results describes changes in baseline relationships from V1 to V2, V2 to V3, and V1 to V3. Furthermore, we looked at what changes in our outcome variables (QOL, PHQ-9, and relative BMI) could be attributed to our baseline V1 demographics and relationships.

Baseline Sample Description-Research Question 1

This study includes 267 children and associated caregivers, who initiated treatment at the PHWRTC in July, 2007 and were followed through November, 2009. Of these 267, 113 (42% of the original group) returned for a second visit (V2), and 48 (18% of the original group) returned for a third visit (V3). The characteristics of children and caregivers who comprised the sample

are detailed in Table 1. The majority of the children were female (54%), black (63%), and under 13 years of age (57%). The mean BMI of the child sample at the initial visit was 37.3 (range 19.6-72.6), the mean BMI z-score was 2.5 (range 1.2-3.6), and the mean percent overBMI was 101.8 (range 19.4-229.0). Over 72% of the children were classified as severely obese at their initial visit, with a median BMI of 36. Less than half of the children were from two-parent families, and 36% were from single parent families. Over 85% of the caregivers at the initial visit were the child's mother. A majority of the caregivers were black (65%), had an associate degree, some college or a college degree (62%), and were employed (69%). The median age of the caregivers was 39, with ages ranging from 25 to 69. Less than 17% of the caregivers had traditional health insurance, and almost half of them were on Medicaid.

For select race-specific analyses our most prevalent groups were white and black, therefore we dropped our sample from 267 to 249, excluding child and caregiver pairs who were a race other than white or black. According to the guidelines put forth by the *Expert Recommendations* there were 5 (1.9%) children who were classified as "overweight," 68 (25.5%) as "obese," and 194 (72.7%) as "severely obese." For select BMI category analyses, the most prevalent groups: "obese" and "severely obese" were used.

Baseline Outcome Variables-Research Question 1

QOL

For the total group of children (n=266) the mean total score for the PedsQL was 73.0 (range 19-100) with a standard deviation (SD) of 15.0. The psychosocial mean score was 72.0 (range 10-100) with a SD of 17.6. For the individual functioning subscales: the physical mean was 77.2 (range 25-100) with a SD of 15.7, emotional mean was 72.1 (range 10-100) with a SD

of 21.7, social mean was 71.9 (range 0-100) with a SD of 22.2, and school mean was 70.0 (range 0-100) with a SD of 18.9.

For the total group of caregivers (n=267) the mean total score for the PedsQL on the report of their child's functioning was 66.2 (range 14-100) with a SD of 18.2. The psychosocial mean score was 66.7 (range 17-100) with a SD of 18.9. For the individual functioning subscales: the physical mean was 65.38 (range 0-100) with a SD of 21.2, emotional mean was 68.0 (range 10-100) with a SD of 21.9, social mean was 65.4 (range 4-100) with a SD of 22.9, and school mean was 67.3 (range 0-100) with a SD of 21.9.

Depression

The sample was split according to age of children and appropriateness of inventories: there were 147 (55.1%) children 8-12 years old and 120 (44.9%) (teen)agers who were 13-18 years old. At V1 there were 147 children, and 120 teens. Only teens (≥ 13 years old) and caregivers received the PHQ-9, which assessed for depression. The PHQ-9 depression severity scores range from no depression (0-4), mild depression (5-9), moderate depression (10-14), moderately severe depression (15-19), and severe depression (20-27). There were 120 teens and 249 caregivers who completed the PHQ-9. The mean depression score for all teens was 5.7 (range 0-19) with a SD of 4.5; for all caregivers the mean score was 5.4 (range 0-21) with a SD of 4.9. Our participants fell into the two categories of mild (score ≤ 9) and moderate depression (score ≥ 10). For the teens (n=114) 90 (78.9%) had a score ≤ 9 and 24 (21.1%) had a score ≥10. Those caregivers of teenagers (n=114) 89 (78.1%) had a score ≤9 and 25 (21.9%) had a score ≥10. Of the 24 teens who were moderately depressed, only 7 of their caregivers also reported moderate depression.

Baseline Relationships-Research Question 2

BMI Category & QOL

A one-way between-groups analysis was conducted to explore the impact of teen's BMI on teen's scores of QOL. Teen participants were divided into two categories according to their BMI: obese or severely obese. There was a not a statistically significant difference in QOL scores for the two groups categorized by BMI.

The same analysis was used to explore the impact of teen's BMI on caregiver's reported scores of their teens' QOL. There was a statistically significant difference at the $p<.05$ level in QOL scores for the two groups categorized by BMI category and a) the caregiver's total score [$F(1, 260)=5.7$, $p=.018$], b) psychosocial total [$F(1, 260)=4.4$, $p=.037$], and c) the physical subscale [$F(1,260)=5.8$, $p=.017$]. Caregivers of teens who were severely obese rated their child's QOL lower than those caregivers of children who were obese.

Relative BMI & QOL

The relationship between QOL totals and subscales and BMI z-score and percent overBMI was investigated using a Pearson product-moment correlation coefficient. There were not any statistically significant correlations of z-score and percent overBMI with the QOL total score or any of the QOL subscales for the total group, or for the children categorized as <13 and ≥13 years old. All of the correlations had shared variances less than 4 percent. Based on Cohen's (1998) interpretation of correlation strength, there was a small or low, negative correlation between percent overBMI and the physical [$r=-.10$, $n=266$, $p=.103$] and social [$r=-.11$, $n=266$, $p=.075$] subscales, with high levels of relative BMI associated with lower levels of QOL on the physical and social subscales.

For the next analysis we split the sample according to age, those <13 and ≥13 years old. For those children <13, an inverse correlation was demonstrated where lower QOL scores were seen as percent overBMI increased in the child total QOL score [r=-.10, n=147, p=.220] and the physical [r=-.19, n=147, p=.02] subscale, with high levels of relative BMI associated with lower levels of QOL on the total score and physical subscale. For those children ≥13, a similar inverse correlation was seen where there was a small or low, negative correlation between percent overBMI and the child psychosocial total [r=-.11, n=119, p=.227] and emotional [r=-.12, n=119, p=.187] and social [r=-.18, n=119, p=.052] subscales, with high levels of relative BMI associated with lower levels of QOL on the psychosocial total and emotional and social subscales.

For those children <13, there was a small or low, negative correlation between BMI z-score and the child physical [r=-.13, n=147, p=.120] subscale, with high levels of relative BMI associated with lower levels of QOL on the physical subscale. For those children ≥13, there was a small or low, negative correlation between BMI z-score and the child psychosocial total [r=-.11, n=119, p=.222] and the emotional [r=-.11, n=119, p=.222] and social [r=-.16, n=119, p=.079] subscales. These results indicate a weak inverse relationship; as relative BMI decreased the child psychosocial total and emotional and social subscales increased.

Relative BMI & Child Depression

There were not any statistically significant correlations of z-score or percent overBMI with the PHQ-9 total score.

QOL & Depression

A one-way anova was used to compare QOL mean total score and subscale mean scores between teen's categorized with no depression or low level of depression (PHQ-9 total score ≤9) and teen's categorized with moderate levels of depression (PHQ-9 total score ≥10). For the total

QOL and all QOL subscales, the mean scores for teen's with moderate depression were significantly lower than the teen's with PHQ scores ≤9 ($p<.001$). There was a statistically significant difference in QOL scores for the two groups categorized by depression level of the teen's total score [$F(1,117)=37.7$, $p=.000$], psychosocial total [$F(1,117)=29.7$, $p=.000$], and all subscales (physical [$F(1,117)=37.1$, $p=.000$] , emotional [$F(1,117)=24.2$, $p=.000$], social [$F(1,117)=15.1$, $p=.000$], and school [$F(1,117)=21.3$, $p=.00$]. Teens who had a moderate depression level, perceived their QOL to be lower on the total and subscale scores. Large effect sizes measured with Eta squared were observed for all comparisons except for social QOL which had a moderate effect size.

The same analysis was used to explore the impact of caregiver's depression level on caregiver's reported scores of their teens' QOL. Caregiver participants were divided into two groups according to their depression level: mild and moderate according to the total score on the PHQ-9. There was a statistically significant difference at the $p<.05$ level in QOL scores for the two groups categorized by depression level of the caregiver's total score [$F(1,118)=12.7$, $p=.001$], psychosocial total [$F(1,118)=12.7$, $p=.001$], and the physical [$F(1,118)=6.7$, $p=.011$] , emotional [$F(1,118)=22.5$, $p=.000$], and social [$F(1,118)=8.0$, $p=.006$] subscales. Caregivers who personally experienced a moderate depression level perceived their teen's QOL to be lower on all totals and subscale scores, except for the school subscale.

BMI Category & Depression

A chi-square test for independence indicated no statistically significant difference between depression level and BMI category (obese or severely obese), with 21.1% of severely obese with moderate depression and 17.2% of obese with moderate depression ($\chi 2$ [1, n=119] = 0.20, p = .65).

Differences between Groups at Baseline-Research Question 2

QOL & Contextual Variables

A one-way anova was used to compare QOL mean total score and subscale mean scores between children categorized by gender and race (white male, black male, white female, black female) for the total group and for children aged <13 and teens ≥13. Because of the multiple significance testing required for this analysis, a significance level of .01 was used to control the type I error. Although there were substantial group differences, none of the mean comparisons were statistically significant. For the total group, all mean QOL scores were similar across the gender by race groups.

Overall, white females had the lowest QOL total score (M=71.8), psychosocial total (M=70.0), and physical (M=75.3), emotional (M=66.5), and social (M=69.5) subscale totals. Males, independent of race, had the highest QOL physical (WM M=78.7, BM M=79.1) and emotional (WM M=75.3, BM M=76.6) subscale score. White children, independent of sex, had the highest QOL school (WM M=69.4, WF M=72.0) subscale score and of all the sex/race breakdowns black females scored the highest on the social (M=73.7) subscale of the QOL.

When stratified by age group (children <13 and teens ≥13) white female teens scored lower than white female children (and black children and teens) on all total scores and subscale scores, with the exception of black female children who scored the lowest on the school subscale.

Depression & Contextual Variables

We conducted a chi-square test for independence to determine if the proportion of teens who have mild or moderate depression is the same for males and females and blacks and whites. Teen participants were divided into groups based on their depression level (mild or moderate),

and sex/race. There were not any statistically significant differences. The proportion of teens that have mild or moderate depression does not differ based on sex/race. We ran the same analysis for caregiver's depression and teens race/sex. There were not any significant differences.

BMI Category & Contextual Variables

A chi-square test for independence was used to compare the proportion of severely obese in children categorized by gender and race for children aged <13 and teens ≥13 (Table X). For the total group, obesity level and sex/race were significantly related ($\chi 2$ [3, n=245] = 13.49, p = .004). The percentage of severely obese white males and black males were 72% and 87% respectively, and the percentage of severely obese white females and black females were 55% and 69% respectively.

For children <13, obesity level and sex/race were significantly related ($\chi 2$ [3, n=132] = 12.07, p = .007). The percentage of white males and black males severely obese were 65% and 89% respectively, and the percentage of white females and black females severely obese were 45% and 71% respectively. There were significantly more black males and significantly fewer white females that were severely obese than expected. For teens >=13, obesity level and sex/race were not significantly related. The percentage of white males and black males severely obese were 85% and 85% respectively, and the percentage of white females and black females severely obese were 65% and 68% respectively.

Longitudinal Relationships-Research Questions 3

Relative BMI

The mean (SD) BMI z-score and percent overBMI for those children who only had a V1 and V2 and the mean change in BMI z-score and percent overBMI from V1-V2, V2-V3, and V1-V3 are displayed in Table 2. In addition, the relative BMI and mean change for those who had a

V1, V2, and V3 are detailed in Table 3. We also controlled for time between visits, see "Adj. Time." There was a gradual decrease for both measures in the total group from V1-V2 (n=113) and V1-V3 (n=48).

Relative BMI & QOL over Time

The relationship between days between visits and relative BMI was investigated using a Pearson product-moment correlation coefficient. There was a small or low, negative correlation between percent overBMI and days between V1-V2 [r=-.26, n=113, p=.006], with more days between V1-V2 associated with lower levels of relative BMI (specifically percent overBMI). The effect size described less than 10% of the shared variance. We ran the same correlations for V2-V3 and V1-V3, which resulted in no statistically significant results for any measures of relative BMI.

Before we controlled for time between visits, we conducted a one way between groups ANOVA to determine if there was a difference in days between visits and measures of relative BMI for children from V1-V2 and V2-V3. Children divided into categories based on those who had a follow up visit < 90 days from their initial visit and > 90 of their visit. For V2-V3 children were divided into categories based on those who had a V3 visit < 180 days from their second visit and > 180 days. Although there were not any statistically significant results from V1-V2 or V2-V3, from V1-V2 the group of children who had a visit < 90 days from their initial visit had an overall decrease in their relative BMI, and those who had a visit > 90 days from their initial visit had an overall increase in their relative BMI (specifically percent overBMI).

Relative BMI & QOL over Time

Days between V2 and V3 was $\bar{x}$=111 (range 31-382) and V1 to V3 was $\bar{x}$=194 (range 91-431). Time between V1 and V2 was on average 104 days (range 25-612), which is equal to about

three and half months. After we adjusted for time with QOL from V1-V2 we conducted a Pearson product-moment correlation coefficient to determine if relative BMI was associated with QOL. There were not any statistically significant or large effect sizes for any measures of QOL for the total group. There was a small effect size for BMI z-score and the QOL total score [r=.10, n=113, p=.280] and physical [r=.13, n=113, p=.178] subscale. It appeared that relative BMI is not related to overall QOL improvement.

Changes in QOL over Time

In Tables 4 and 5 the results of a paired samples t-test were conducted to evaluate the children's and caregivers' perceptions of QOL from V1 to V2, V2 to V3, and V1 to V3 was described. From V1 to V2 there was a statistically significant difference ($p<.0005$) on the total score, psychosocial total, and for all subscale scores (physical, emotional, social, and school). From V2 to V3 there was a statistically significant difference at the ($p<.05$) on the total score, psychosocial total, and emotional subscale. From V1 to V3 there was a statistically significant difference ($p<.005$) on the total score, psychosocial total, and the emotional, social, and school subscales.

Teen and Caregiver Depression over Time

We ran a chi-square test for independence to determine if the teen was more likely to be depressed from V1, V2, and V3. All teenagers who were moderately depressed at V1 (n=23) resolved their depressive symptoms by V3, meaning they had a score < 9. Of the 23 children who had moderate depression at V1, only five of their caregiver pairs had moderate depression; indicating that teen and caregiver depression was not related (statistically speaking).

Depression and QOL over Time

After adjusting for time from V1 to V2 the relationship between QOL totals and subscales and PHQ-9 score was investigated using a Pearson product-moment correlation coefficient. There was a large correlation between the PHQ-9 score and total QOL score [r=.65, n=52, p=.000], psychosocial total [r=.62, n=52, p=.000] and physical [r=.50, n=52, p=.000] and emotional [r=.64, n=52, p=.000] subscales. There was medium effect for the social [r=.37, n=52, p=.006] and school [r=.45, n=52, p=.001] subscales. Therefore, improvement in the total PHQ-9 score was strongly related to QOL improvement.

Longitudinal Relationships-Research Question 4

Changes in QOL & BMI Category over Time

In Table 6 the results of a paired sample t-test conducted to evaluate the impact of QOL changes and BMI category (obese and severely obese) from V1 to V2, V2 to V3, and V1 to V3 was described. From those children who were categorized as "obese" from V1 to V2, there was a statistically significant increase ($p<.05$) on the QOL total score, psychosocial total, and emotional, social, and school subscales. For those who were categorized as "severely obese" from V1 to V2, there was a statistically significant increase ($p<.05$) on the QOL total score, psychosocial total, and on all subscale scores. Those children who were categorized as "obese" or "severely obese" from V1 to V2 had significant improvements in their QOL, despite their weight category.

For those categorized as "obese" from V1 to V3, there was a statically significant increase ($p<.05$) for the QOL total score, psychosocial total, and school subscale score. For those categorized as "severely obese" from V1 to V3, there was a statistically significant increase ($p<.05$) for the QOL total score, psychosocial total, and emotional subscale score. Those children

who were categorized as “obese” or “severely obese” from V1 to V3 had significant improvements in their QOL, despite their weight category.

Sex-Race & Relative BMI and QOL

After controlling for time, we split our sample according to sex and race. In Table 7 the results for sex-race relationships were described between 1) relative BMI (BMI z-score and percent overBMI); 2) QOL, and 3) PHQ-9 (teen). Overall BMI z-score related more strongly to QOL than percent overBMI for black males; however, for white males, percent overBMI related more strongly to QOL. In comparisons between males and females, relative BMI (BMI z-score and percent overBMI) related more strongly to QOL for males. For depression, the PHQ-9 total was strongly associated with QOL for black teens (male and female), with no significant association for white teens.

Discussion

In order to seek out longitudinal changes through integrated care treatment, we developed a protocol for assessing BPS indicators for overweight children and their caregivers. For the purpose of this study, we were particularly curious about changes from baseline variables in QOL, depression level, and relative BMI (both BMI z-score and percent overBMI) over time. Overall, across three visits (V1-V2-V3), our results indicated children’s BMI z-score and percent overBMI decreased slightly, their QOL significantly increased, and their depression level improved. Likewise, caregivers’ perception of their child’s QOL increased across three visits. Our research was unique in that it was a longitudinal clinical sample of overweight children in which our results indicated improvement in QOL (child and caregiver perspectives), depression, and relative BMI. Specifically, our sex, race, and age breakdowns for relative BMI indicated that both BMI z-score and percent overBMI were sensitive to different populations. The following

paragraphs detail unique outcomes from this study especially in relation to QOL and 1) contextual variables, 2) BMI category, 3) depression, and 4) relative BMI followed by limitations, clinical implications, and recommendations.

Similar to previously published research on QOL (Pinhas-Hamiel et al., 2006; Zeller & Modi, 2006), caregivers in our sample (independent of sex and race) perceived their child's QOL to be lower than the child's reported QOL; however other researchers have indicated that children rated their QOL higher than their caregivers report of child QOL (Williams et al, 2005). Our sample also had similar findings as previous researchers on QOL and contextual variables (e.g., boys reported more favorably on their physical functioning (Janicke, 2007) and girls reported more impaired social functioning (Zeller et al., 2006). However our results offered a new contribution pertaining to age and race/sex, in that white teenage girls (independent of age) had the most impaired QOL; whereas white teenage males had consistently higher scores on all measures of QOL. This result punctuates the need for a qualitative investigation to better explore QOL in relation to experiences with and acceptance of being overweight, giving specific attention to contextual variables (i.e., age, race, and sex).

Interestingly, all children from V1 to V2 and V1 toV3 had significant improvements in their QOL, despite their BMI category. The most significant QOL improvement was seen in children who were severely obese on the emotional subscale. This is especially important to consider, given that other researchers have reported that quality of life is inversely related to weight; as a child's weight increased, her QOL decreased, suggesting that the most overweight children have the most significantly impaired QOL (Zeller, Roehrig, Modi, Daniels, & Inge, 2006). In a cross-sectional study, Williams et al. (2005) compared children of different BMI categories (normal, overweight, obese). In that research, obese children were found to have a

lower QOL than their normal and overweight peers. However, we couldn't find longitudinal research that focused on differences between children in different severity categories of obesity (i.e., obese vs. severely obese); our results indicate that even those who are most impacted by the obesity epidemic (severely obese or $\geq 99^{th}$ percentile) had positive results in QOL.

Previous researchers have documented that caregiver perceptions were similar to child evaluations of QOL, independent of weight category (Williams, Wake, Hesketh, Maher, & Waters, 2005). However, in our sample BMI category negatively influenced caregiver's perceptions of their child's QOL; as those who were considered severely obese (in comparison to obese) received lower QOL outcomes based on caregiver perspective. A hopeful finding is that over time (V1-V3) the caregiver's perspective on child's QOL improved.

Another interesting caregiver perspective was that caregivers who had moderate (rather than mild) depression perceived their child's QOL to be lower. Pott et. al. (2009), found no significant association between childhood obesity and maternal depression, however when we looked at how caregiver depression may impact the way the caregivers view their child's QOL functioning, there were significant results. Similar to caregivers, teens who had moderate depression also perceived their QOL to be lower. After adjusting for time, improvement in teen depression (PHQ-9 score) was strongly related to QOL improvement. The teen PHQ-9 total had a stronger association with QOL for black teens (male and female) than white teens. This result gives strength to the need for clinicians to assess for depression (in the teen and caregiver) in tandem with a QOL inventory. While past researchers have assessed for child or caregiver depression and for QOL (Swallen et al., 2005), no known researchers have assessed for child and caregiver depression longitudinally in tandem with a QOL inventory. The longitudinal results offer an especially unique contribution to this literature.

Although our research questions did not set out to compare relative measures of BMI, we decided to use both BMI z-score and percent overBMI in our analyses. Paluch et al. (2007) concluded that BMI z-score is not the most sensitive measure of relative BMI in longitudinal samples; whereas percent overBMI tends to show a higher level of sensitivity over time. In our sample, from V1-V3 we had a greater decrease in percent overBMI than BMI z-score. We also found percent overBMI to be more sensitive in our baseline correlations with QOL. In our total group at V2 (n=113), it appeared that relative BMI was not related to overall child QOL improvement. However, after we adjusted for time, BMI z-score related more strongly to QOL than percent overBMI for black males. For white males, percent overBMI related more strongly to QOL. Overall, both measures of relative BMI related more strongly to QOL for males than females, regardless of race. To date, we could not find literature to contrast or compare our results, especially with one measure of relative BMI having greater sensitivity toward certain contextual (i.e., sex/race) populations than others. Given these results, which show BMI z-score to be more sensitive in certain populations (black males) and percent overBMI (white males) in other populations, it may be more beneficial to use both measures of relative BMI to better understand diverse samples.

Limitations

One important limitation of our study is the small sample size (n=267) due to the number of factors (e.g., rural setting, low SES population, and limited public transportation) that make follow-up visits difficult, at our clinic. In order to generate a comprehensive and longitudinal picture of how obesity affects children and their caregivers, a larger sample size and greater continuity in follow up care is important.

Finally, as a stage three childhood obesity treatment center, we should ideally see children every week for follow-up appointments (Barlow, 2007). However, the need in our rural-underserved area allows us to see children at monthly intervals, at best. Our results indicated that children who had the greatest amount of days between visits, gained more weight. It is important for childhood obesity treatment centers, including our own, to figure out ways our healthcare providers, administration, and financial parties can work together to ensure the availability of consistent follow-up appointments, especially for those children who are above the 95th percentile.

Clinical Implications

The PHWRTC bolsters a stage three (Barlow, 2007), family-centered integrated approach; in such a setting it is common for sensitive factors central to family communication and adherence to goals to be openly discussed and explored with healthcare providers and the family. Based on our results, we believe several key findings may be important for clinicians/providers to consider in their assessment and interview. 1) Appreciate that caregivers may overestimate the impact that a child's weight has on their QOL. Hence, in interviews parents/guardians may speak about the child's overall problems in school and with friends and family with their perspective hindered due to weight. 2) Recognize that children and caregivers who have moderate to severe depression may believe their QOL to be lower than those children who aren't depressed. Children and/or caregivers who are depressed may need to address their depression before focusing on goals that may otherwise influence quality of life. 3) If resources allow, promote frequent follow-up with families at more intense intervals (i.e. every week as recommended). 4) Utilize both measures of relative BMI (BMI z-score and percent overBMI) for diverse populations in sex and race.

Research Recommendations

In accordance with the *Expert Recommendations,* a family-centered approach should be used by clinicians to address obesity in children, which simultaneously charges childhood obesity researchers to find assessments that not only capture measures of obesity but also measures of child, caregiver, and family health-related functioning (e.g., parental depression). In order to address the different biopsychosocial ways obesity can manifest for a child and their family we suggest using measures (with good psychometrics) such as the PedsQL to explore perceptions of children's QOL and caregiver's perception of children's QOL and the PHQ-9 to assess depression in teens and caregivers. In order to remain family focused, we also believe the discrepancy between children's and caregiver's QOL perceptions and the relationship this discrepancy may have on BMI and depression should be investigated. Although both the PedsQL and PHQ-9 were used systemically, including more relational assessments is important in order to address challenges such as family conflict, parenting style, and stress level. We also encourage researchers to track children longitudinally throughout the entire duration they are involved with a treatment program in order to investigate the relationship between children's QOL and those who level or decline in BMI verses those who increase or gain; specifically, if there is a certain QOL threshold that children may reach before they begin to show signs of weight loss.

Tables

Table 1. Baseline and Longitudinal Characteristics						
Child Background						
	Visit 1 267		*Visit 2 113*		*Visit 3 48*	
	n	*%*	*n*	*%*	*n*	*%*
Sex						
Male	122	45.7	44	38.9	20	41.7
Female	145	54.3	69	61.1	28	58.3
Race						
White	80	30.0	39	34.5	20	41.7
Black	169	63.3	70	61.9	28	58.3
Other	18	6.7	4	3.6	0	00.0
Anthropometric Data						
	mean(SD)		*mean(SD)*		*mean(SD)*	
BMI	37.8(12.2)		38.2(8.7)		38.9(9.3)	
BMI z-score	2.50(.34)		2.52(.33)		2.53(.40)	
Percent overBMI	101.8(39.4)		104.5(39.5)		105.1(41.8)	
	n	*%*	*n*	*%*	*n*	*%*
BMI Category						
Overweight	5	1.9	0	0	1	2.1
Obese	68	25.5	39	26.5	11	22.9
Severely Obese	194	72.7	83	73.5	36	75
Baseline Family Background						
	n	*%*		*n*	*%*	
Family Structure						
Two-parent	128	47.9	*Occupational Status*			
Single parent	95	35.6	Employed	184	68.9	
Single parent + Grandparent	27	10.1	Unemployed	73	27.3	
Other	17	6.4				
Relation to Pt.						
Mother	229	85.7				
Father	18	6.7				
Grandparent	15	5.6				
Other	5	1.9				
Insurance						
Traditional	45	16.9				
Medicaid	132	49.4				
CHIP	47	17.6				
Other	39	14.6				
Baseline Caregiver Background						
	n	*%*		*n*	*%*	
Age	256 (M= 40.6,SD 8.4)		*Educational Level*			
Sex			Grammar school	3	1.1	
Male	20	7.5	Some high school	23	8.6	
Female	247	92.5	High school	54	20.2	
Race			Some college	75	28.1	
White	85	31.8	Associates degree	57	21.3	
Black	173	64.8	College	21	7.9	

			degree			
Other	9	3.4	Graduate school	15	5.5	
			Other	6	2.2	

*Values are expressed as mean(SD)

Table 2.
Child Relative BMI Changes for Children with a V1 and V2 Appointment

	n=113		
Variable	*V1*	*V2*	*V1-V2*
	Mean	Mean	*Adj. Mean Dif.
Percent over BMI	104.7(39.09)	104.5(39.5)	.184(2.01)
BMI z-score	2.53(.32)	2.52(.34)	.003(.02)

* Adj. Mean Dif.= adjusted for days between visits.

Table 3
Child Relative BMI Changes for Children with a V1, V2, and V3 Appointment

	n=48					
Variable	*V1*	*V2*	*V3*	*V1-V2*	*V2-V3*	*V1-V3*
	Mean	Mean	Mean	*Adj. Mean Dif.	Adj. Mean Dif.	Adj. Mean Dif.
Percent over BMI	107.23(42.59)	106.37(42.59)	105.11(41.75)	.456(2.16)	.358(2.15)	.399(1.54)
BMI z-score	2.55(.35)	2.54(.36)	2.53(.40)	.003(.02)	.006(.04)	.005(.02)

* Adj. Mean Dif.= adjusted for days between visits.

Table 4.
Child QOL Changes from V1-V2, V2-V3, and V1-V3

Variable	*V1-V2* (n=113)				*V2-V3* (n=48)				*V1-V2* (n=48)			
	Mean(SD)	**Adj. Mean Dif.	Mean Dif.	*P*	Mean(SD)	Adj. Mean Dif.	Mean Dif.	*P*	Mean(SD)	Adj. Mean Dif.	Mean Dif.	*P*
Total Score	***V1** 73.0(15.0) **V2** 78.8(13.5)	2.2(5.2)	5.8(11.6)	.000	**V2** 77.6(13.5) **V3** 80.3(14.1)	.99(2.9)	2.7(8.4)	.029	**V1** 74.3(14.3) **V2** 77.6(13.5)	1.4(4.4)	3.3(10.3)	.031
Psychosocial Total	71.4(16.5) 77.3(14.8)	2.2(5.5)	5.9(12.5)	.000	76.9(14.4) 80.4(13.6)	1.1(3.8)	3.5(9.8)	.018	72.5(16.8) 76.9(14.4)	1.9(5.0)	4.5(11.6)	.010
Sub-Scales												
Physical	75.9(16.0) 81.6(14.5)	2.1(6.8)	5.7(14.3)	.000	79.0(14.3) 80.3(18.6)	.75(3.5)	1.3(11.6)	.451	77.8(12.1) 79.0(14.3)	.35(5.4)	1.2(11.8)	.499
Emotional	70.8(21.0) 78.1(18.4)	2.9(9.0)	7.4(18.9)	.000	76.9(17.6) 82.1(16.7)	2.0(6.1)	5.3(15.4)	.022	71.3(19.4) 76.9(17.6)	2.5(8.9)	5.6(18.1)	.038
Social	70.9(21.0) 77.2(18.9)	2.9(9.0)	6.4(18.0)	.000	76.2(17.8) 79.4(16.9)	2.0(6.1)	3.3(11.8)	.062	73.8(18.9) 76.2(17.8)	2.5(8.9)	2.4(16.9)	.326
School	70.3(19.2) 75.1(18.1)	2.1(5.9)	4.8(14.6)	.001	75.8(16.4) 78.3(16.9)	.78(4.9)	2.6(12.0)	.142	70.2(19.6) 75.8(16.4)	2.6(6.6)	5.6(1.9)	.006

*Will be the format for the remaining rows.
**Adj. Mean Dif. = adjusted for days between visits.

Table 5.
Caregiver QOL Changes from V1-V2, V2-V3, and V1-V3

Variable	*V1-V2* (n=113)				*V2-V3* (n=46)				*V1-V2* (n=46)			
	Mean(SD)	** Adj. Mean Dif.	Mean Dif.	*P*	Mean(SD)	Adj. Mean Dif.	Mean Dif.	*P*	Mean(SD)	Adj. Mean Dif.	Mean Dif.	*P*
Total Score	***V1** 64.3(17.7) **V2** 69.8(18.0)	1.8(8.0)	5.5(17.6)	.001	**V2** 68.9(16.8) **V3** 67.6(14.0)	-.68(5.0)	-1.4(14.3)	.525	**V1** 62.1(16.0) **V2** 68.9(16.8)	2.3(9.5)	6.8(19.7)	.024
Psychosocial Total	64.4(18.9) 71.0(18.1)	2.1(6.6)	6.5 (15.5)	.000	69.5(17.4) 70.5(14.9)	.26(3.9)	-.98(12.4)	.595	62.6(16.8) 69.5(17.4)	2.3(8.3)	6.9(17.6)	.011
Sub-Scales												
Physical	64.0(19.5) 67.6(22.2)	1.2(12.6)	3.6(26.7)	.152	67.9(20.2) 62.2(19.6)	-2.4(9.7)	-5.7(24.2)	.116	61.1(17.5) 67.9(20.2)	2.2(13.1)	6.8(27.2)	.099
Emotional	66.5(22.7) 72.2(20.5)	1.8(8.7)	5.8(18.9)	.002	68.6(19.3) 73.4(19.6)	1.7(6.9)	4.8(19.3)	.101	63.8(19.6) 68.6(19.3)	1.2(9.4)	4.8(20.4)	.116
Social	62.5(22.8) 71.2(21.2)	2.7(7.6)	8.6(18.8)	.000	70.9(21.1) 69.7(18.7)	-.70(4.9)	-1.2(16.5)	.626	59.6(19.4) 70.9(21.1)	3.6(9.4)	11.3(22.3)	.001
+School	64.8(23.0) 70.3(21.5)	2.0(8.6)	5.5(20.4)	.005	69.3(20.9) 68.8(18.6)	-.19(5.4)	-.53(17.7)	.842	65.0(21.2) 69.3(20.9)	2.0(9.7)	4.3(20.2)	.159

*Will be the format for the remanding rows.
-=decrease between second and third visit in QOL
** Adj. Mean Dif.= adjusted for days between visits.
+Slight variability in n size

Table 6.
Child QOL Changes from V1-V2, V1-V3, and V2-V3 by BMI Category

Variable	*V1-V2 (n=113)*				*V1-V3 (n=48)*				*V2-V3 (n=48)*			
	Mean(SD)	**Adj. Mean Dif.	Mean Dif.	*P*	Mean(SD)	Adj. Mean Dif.	Mean Dif.	*P*	Mean(SD)	Adj. Mean Dif.	Mean Dif.	*P*
Total Score												
Obese	(n=29) ***V1** 70.8(16.6) **V2** 77.9(14.9)	2.5(6.2)	7.16(13.1)	.006	(n=10) **V1** 76.5(12.0) **V3** 85.4(5.9)	1.3(1.8)	8.91(11.0)	.030	(n=10) **V2** 80.8(9.0) **V3** 85.4(5.9)	1.6(2.8)	4.7(6.7)	.054
Severely Obese	(n=84) **V1** 73.7(14.4) **V2** 79.1(13.1)	2.0(4.9)	5.39(11.1)	.000	(n=38) **V1** 73.7(15.0) **V3** 79.0(15.4)	1.0(2.6)	5.27(13.0)	.017	(n=38) **V2** 76.8(14.4) **V3** 79.0(15.4)	.83(3.0)	2.2(8.8)	.129
Psychosocial Total												
Obese	69.1(18.6) 76.7(16.9)	2.6(5.5)	7.59(14.0)	.007	75.0(16.4) 84.3(7.1)	1.3(2.3)	9.33(12.8)	.046	81.5(10.7) 84.3(7.1)	.88(3.5)	2.8(8.9)	.338
Severely Obese	72.1(15.8) 77.6(14.1)	2.1(5.5)	5.37(11.9)	.000	71.2(17.0) 79.4(14.8)	1.4(2.9)	7.58(13.9)	.002	75.7(15.1) 79.4(14.8)	1.2(3.9)	3.7(10.1)	.033
Subscales												
Physical												
Obese	73.8(18.3) 80.2(15.0)	2.4(9.4)	6.36(16.8)	.051	79.4(5.6) 87.5(8.5)	1.4(2.3)	8.13(12.4)	.069	79.4(10.1) 87.5(8.5)	3.0(3.2)	8.1(9.2)	.021
Severely Obese	76.6(15.2) 82.1(14.3)	1.9(5.7)	5.47(13.5)	.000	77.4(13.4) 78.3(20.1)	.25(3.4)	.94(17.7)	.745	78.9(15.3) 78.3(20.1)	.17(3.4)	-.53(11.6)	.780
Emotional												
Obese	67.1(24.3) 76.7(21.2)	3.5(9.0)	9.66(21.5)	.022	75.5(19.8) 82.0(14.6)	.86(4.1)	6.50(21.5)	.364	79.5(14.2) 82.0(14.6)	.92(6.0)	2.5(16.2)	.637
Severely Obese	72.0(19.6) 78.6(17.5)	2.7(9.1)	6.59(18.1)	.001	70.2(19.4) 82.2(17.4)	2.2(3.3)	12.01(17.5)	.000	76.2(18.5) 82.2(17.4)	2.2(6.1)	6.0(15.3)	.021
Social												

Obese	70.3(24.8) 76.7(22.3)	1.9(5.3)	6.47(14.8)	.026	77.1(20.3) 85.0(17.9)	1.3(2.1)	7.92(11.5)	.058	82.1(13.2) 85.0(18.0)	1.1(5.3)	2.9(15.0)	.553
Severely Obese	71.1(19.7) 77.4(17.8)	2.2(7.3)	6.33(19.0)	.003	72.9(18.7) 78.0(16.5)	1.0(3.3)	5.07(16.9)	.073	74.7(18.7) 78.0(16.5)	.79(3.7)	3.3(11.0)	.070
School												
Obese	68.8(16.0) 75.9(19.3)	2.5(4.7)	7.07(13.1)	.007	71.5(12.7) 84.0(11.3)	1.8(2.1)	12.50(16.5)	.041	81.5(12.7) 84.0(11.3)	.44(3.2)	2.5(8.6)	.381
Severely Obese	70.8(20.2) 74.8(17.8)	1.9(2.1)	4.00(15.1)	.017	69.9(21.2) 76.8(18.0)	1.4(4.6)	6.97(21.5)	.052	74.2(17.0) 76.8(18.0)	.87(5.2)	2.6(12.8)	.216

*this will be the format for the remain rows of the table

-=decrease in QOL

**Adj. Time = adjusted days between visits

Table 7.
Sex/Race Relationships between QOL, PHQ-9, and Relative BMI from V1-V2 (adjusted for time)

Variable	*White Male (n=15)*		*White Female (n=24)*		*Black Male (n=29)*		*Black Female (n=41)*	
	r value	*P*	r value	*P*	r value	*P*	*r value*	*P*
Total Score								
PHQ-9	(n=7) .43**	.334	(n=11) .38**	.256	(n=14) .87***	.000	(n=19) .68***	.001
Percent over BMI	.34**	.223	.05	.836	.16*	.412	-.12*	.454
BMI z-score	.24*	.393	-.06	.771	,49**	.007	-.04	.797
Psychosocial Total								
PHQ-9	.22*	-.057	.33**	.318	.80***	.001	.75***	.000
Percent over BMI	.42**	.123	-.14*	.510	.17*	.384	-.14*	.390
BMI z-score	.37**	.171	-.24*	.256	.51***	.005	-.10*	.531
Physical Subscale								
PHQ-9	.61 ***	.146	.22*	.524	.87***	.000	.47**	.044
Percent over BMI	.06	.844	.40**	.055	.11*	.572	-.08	.626
BMI z-score	-.11*	.703	.36**	.085	.35**	.064	.04	.815
Emotional Subscale								
PHQ-9	-.06	.904	.27*	.424	.70***	.006	.83***	.000
Percent over BMI	.27**	.329	-.14*	.514	.12*	.524	-.12*	.441
BMI z-score	.22*	.425	-.20*	.355	.44**	.018	-.04	.792
Social Subscale								
PHQ-9	.55***	.204	.21*	.531	.58***	.030	.48**	.037
Percent over BMI	.39**	.155	.17*	.435	-.03	.874	-.02	.891
BMI z-score	.28*	.320	.07	.735	.36**	.056	-.03	.854
School Subscale								
PHQ-9	-.08	.870	.38**	.256	.70***	.005	.52***	.023
Percent over BMI	.35**	.199	-.25*	.232	.33**	.084	-.14*	.399
BMI z-score	.40**	.145	-.32**	124	.48**	.009	-.17*	.288

***=large or big effect
**-moderate or medium effect
*=small or little effect

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Appendix A: Institutional Review Board

University and Medical Center Institutional Review Board
East Carolina University • Brody School of Medicine
600 Moye Boulevard • Old Health Sciences Library, Room 1L-09 • Greenville, NC 27834
Office **252-744-2914** • Fax **252-744-2284** • **www.ecu.edu/irb**
Chair and Director of Biomedical IRB: L. Wiley Nifong, MD
Chair and Director of Behavioral and Social Science IRB: Susan L. McCammon, PhD

TO: Keeley Pratt, MS, CDFR, ECU

FROM: UMCIRB

DATE: June 23, 2009

RE: Expedited Continuing Review of a Research Study

TITLE: "Medical Family Therapy Meets Childhood Obesity and Diabetes"

UMCIRB #08-0419

The above referenced research study was initially reviewed and approved by expedited review on 7/21/08. This research study has undergone a subsequent continuing review using expedited review on 6/15/09. This research study is eligible for expedited review because it is research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.). The Chairperson (or designee) deemed this **unfunded** study **no more than minimal risk** requiring a continuing review in **12 months**. Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The investigator must adhere to all reporting requirements for this study.

The above referenced research study has been given approval for the period of **6/15/09** to **6/14/10**. The approval includes the following items:

- Continuing Review Form (dated 6/2/09)
- Protocol Summary
- Consent Document: Caregiver of the Pediatric Healthy Weight Patient
- Consent Document: Caregiver of the Pediatric Diabetes Patient
- Background Survey: Caregiver
- Minor Assent: Pediatric Healthy Weight Patients aged 5-17
- Minor Assent: Pediatric Diabetes Patients aged 5-17
- PedsQL 4.0, ages 5-18, Patient/Parent
- PedsQL Diabetes Module 3.0, ages 8-18, Patient/Parent
- Patient Health Questionnaire (PHQ-9)
- Fatigue Inventory

- Caregiver & Child Strengths & Concerns Form

The Chairperson (or designee) does not have a conflict of interest on this study.

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.

UMCIRB #: [illegible]

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UNIVERSITY AND MEDICAL CENTER INSTITUTIONAL REVIEW BOARD
REVISION FORM

RECEIVED
JUN 3 8 2009
UMCIRB

UMCIRB #: [illegible] Date this form was completed: 6/26/09
Title of research: Medical Family Therapy Meets Childhood Obesity and Diabetes
Principal Investigator: Kelley J. Pratt, MS, MFTA, Doctoral Candidate
Sponsor: none

Fund number for IRB fee collection (applies to all for-profit, private industry or pharmaceutical company sponsored project revisions requiring review by the convened UMCIRB committee):

Fund	Organization	Account	Program	Activity (optional)
		73059		

FAXED 6-26-09

Version of the most currently approved protocol: 07/21/08
Version of the most currently approved consent document: 07/21/08

MAILED 6-29-09

CHECK ALL INSTITUTIONS OR SITES WHERE THIS RESEARCH STUDY WILL BE CONDUCTED:

- [x] East Carolina University
- [ ] Pitt County Memorial Hospital, Inc
- [ ] Heritage Hospital
- [ ] Other
- [ ] Beaufort County Hospital
- [ ] Carteret General Hospital
- [ ] Boice-Willis Clinic

The following items are being submitted for review and approval:

- [x] Protocol: version or date 07/21/08
- [ ] Consent: version or date
- [ ] Additional material: version or date

Complete the following:

1. Level of IRB review required by sponsor: [ ] full [x] expedited
2. Revision effects on risk analysis: [ ] increased [x] no change [ ] decreased
3. Provide an explanation if there has been a greater than 60 day delay in the submission of this revision to the UMCIRB. We are enrolling 350+ participants because of poor patient showing for follow-up appointments. We will stop collecting data in October, 2009.
4. Does this revision add any procedures, tests or medications? [ ] yes [x] no If yes, describe the additional information:
5. Have participants been locally enrolled in this research study? [x] yes [ ] no
6. Will the revision require previously enrolled participants to sign a new consent document? [ ] yes [x] no

Briefly describe and provide a rationale for this revision: We are enrolling 350+ participants because of poor patient showing for follow-up appointments. We will stop collecting data in October, 2009.

Kelley J Pratt — Kelley J Pratt — 6/26/09
Principal Investigator Signature — Print — Date

Box for Office Use Only

The above revision has been reviewed by:
[ ] Full committee review on [ ] Expedited review on 6/29/09

The following action has been taken:
[x] Approval for period of 6/29/09 to 6/29/10
[x] Approval by expedited review according to category 6&7&8&9-11
[ ] See separate correspondence for further required action.

[illegible] MD — [illegible] — 6/29/09
Signature — Print — Date

UMCIRB #: MedFT meets Childhood Obesity and Diabetes 08-0419

UNIVERSITY AND MEDICAL CENTER INSTITUTIONAL REVIEW BOARD
HUMAN BEHAVIORAL AND SOCIAL SCIENCE CONTINUING REVIEW OR STUDY CLOSURE

Note: Each section should be completed regardless of whether this form is being submitted for continuing review or closure of a research study.

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DEMOGRAPHIC INFORMATION

UMCIRB Number: 08-0419 **Date this form was completed:** 6/2/09

Title of research (this title must match protocol, consent form and funding application, if applicable): Medical Family Therapy Meets Childhood Obesity and Diabetes

Principal investigator, credentials, department, section and school: Keeley J. Pratt, M.S., Medical Family Therapy Doctoral Candidate, Child Development and Family Relations, Medical Family Therapy Program, College of Human Ecology, East Carolina University.

Subinvestigators, credential, department, section and schools: L. Angela L. Lamson, PhD, LMFT, CFLE, Associate Professor, Program Director, Child Development and Family Studies, Medical Family Therapy & Marriage and Family Therapy, College of Human Ecology, East Carolina University. [redacted] J. Carmel Parker White, PhD, Assistant Professor, Child Development and Family Studies, College of Human Ecology, East Carolina University.

ITEMS FOR APPROVAL

☒ **Research study being submitted for renewal.**

Version of the most currently approved protocol: 07/21/08
Version of most currently approved consent document: 07/21/08
List all other items that are currently approved (i.e. advertisements, questionnaires, study measures, etc.) and need to be re-approved for new approval period. Listing those items enhances the renewal process to make sure all research items required to conduct the research study will be re-approved:

[redacted]
Impact of Weight on Quality of Life Inventory-removed due to length in time for completion
[redacted]

☐ **No items need to be approved since study is being closed.**

INVESTIGATOR QUALIFICATIONS

☒ **Research study being submitted for renewal.**

Provide the date of completion for the UMCIRB Human Subjects Protections training modules for the principal investigator, any subinvestigators and coordinators if this study is being renewed (must be current within 3 years): Keeley Pratt 01/08, Angela Lamson 02/08, Suzanne Lazorick 08/08, Glenn Harris, 03/07, Carmiel White 12/08

☐ **No UMCIRB Human Subjects Protection training modules information is necessary since study is being**

closed.

Have there been any changes in your credentialing, licensure, certifications or privileges since the last continuing review? ☐ yes ☑ no If yes, describe.

SOURCE OF FUNDING:

☐ Government Agency, Name:
☐ Private Agency, Name:
☐ Institution or Department Sponsor, Name:
☑ no source of funding exists for this research

Fund number for IRB fee collection (applies to continuing review of all for-profit, private industry or pharmaceutical company sponsored projects):

Fund	Organization	Account	Program	Activity (optional)
		73059		

CHECK ALL INSTITUTIONS OR SITES WHERE THIS RESEARCH STUDY WILL BE CONDUCTED:

☒ East Carolina University ☐ Other

AMENDMENTS / REVISIONS / MODIFICATIONS

☐ There have been no amendments, revisions or modifications to the research protocol since the last review.
☑ Yes, there have been amendments, revisions or modifications since the last continuing review. Attach the UMCIRB revision form for any revision that is being considered for approval along with this continuing review. List the title or reference each item including version date and UMCIRB approval date. Addition of the Fatigue Inventory and sub investigator. Carmel White, PhD: 10/13/08

☒ There have been no amendments, revisions or modifications to the consent document since the last review.
☐ Yes, there have been amendments, revisions or modifications to the consent document since the last continuing review. Attach the UMCIRB revision form for any revision that is being considered for approval along with this continuing review. List the title or reference for each the item including version date and UMCIRB approval date.

☒ This is not a grant funded study.
☐ There have been no amendments, revisions or modifications to the grant since the last review.
☐ Yes, there have been amendments, revisions or modifications to the grant since the last continuing review. Attach a copy of the updated grant application with changes outlined or highlighted.

PARTICIPANT ACTIVITY

Sample size proposed in the research	100
Total number of participants enrolled at all research sites to date	238
Total number of participants enrolled at this site since the research was initially approved	238
Total number of participants enrolled at this site since the last continuing review	120
Total number of participants completing all aspects of research at this site since the last review	120
Total number of participants involved in the follow-up portion of the research at this site	120
Total number of participants locally withdrawn prior to research completion	0

Provide specific details regarding all participant withdrawals from the research study, whether voluntary or initiated by the investigator. none to date

Describe any difficulties in participant enrollment, specifically if the enrollment goals have not been reached as originally outlined. Describe the impact this will have on completing the study. none to date

If you have exceeded the sample size initially proposed for this research study, provide a rationale. To reach statistical significance we need at least 100 patients at each visit intreval we are going to consider for analysis.Hence, the larger population size needed. Additinally, the research has not been a hinderance on sevices.

MONITORING AND ONGOING ACTIVITIES

☒ There have been no locally occurring serious adverse events or events resulting in unanticipated risks to participants or others since the last review.
☐ Yes, there have been locally occurring serious adverse events or events resulting in unanticipated risks to participants or others since the last review. Attach an Adverse Event Reporting Form for any previously unreported serious adverse events. Applicable serious adverse events that have previously been reported should be listed by referring to the study participant code/number, date of event, type of event, and date submitted to the IRB office.

☒ There have been no protocol deviations/violations for this research study since the last review.
☐ Yes, there have been protocol deviations/violations for this research study since the last review. Attach a Protocol Deviation Form for any previously unreported protocol deviations/violations. Any protocol deviations/ violations that have previously been reported should be listed by referring to the study participant code/number, date of event, type of event, and date submitted to the IRB office.

☒ There have been no regulatory auditing activities or monitoring visits by a sponsor, institutional officials or outside agency since the last review.
☐ Yes, there have been regulatory auditing activities or monitoring visits by a sponsor, institutional officials or outside agency since the last review. Attach a report of these activities if the outcome was unfavorable or unacceptable. List the auditor/monitor (sponsor, institution, federal agency) and date of the activity.

☒ There has been no analysis or reports by a data monitoring committee since the last review.
☐ There has been an analysis or report by a data monitoring committee since the last review. Attach the report to the continuing review form if not previously submitted. If this report has been previously submitted to the UMCIRB, list that date.

☒ There have been no publications or presentations generated from the local investigator involved in this research since the last review.
☐ There have been publications or presentations generated from the local investigator involved in this research since the last review. List all publications or presentation resulting from information generated by this research generated by local investigators or sponsors. Attach the published materials to the continuing review form.

☒ There have been no new developments generated by this research that have an impact on the assessment of potential risks or benefits for participation in this research study since the last review.
☐ There have been new developments generated by this research that have an impact on the assessment of potential risks or benefits for participation in this research study since the last review. Describe these new developments.

☒ There are no additional comments or information that may be pertinent to the review of this research.
☐ There are additional comments or information that may be pertinent to the review of this research.

CONFLICT OF INTEREST

☒ There are no potential conflicts of interest involving any member of the research team since the last review.

☐ There is now a potential or actual conflict of interest involving a member of the research team since the last review. Complete and attach an updated UMCIRB Conflict of Interest disclosure form.

REQUIRED ATTACHMENTS FOR CONTINUING REVIEW

***Note: To determine whether a research study should go to the full committee for review and approval or if the study can be approved by expedited review, see instructions.

Full Committee Review:

- 2 copies of protocol
- 2 copies of publications/presentations
- 20 copies of continuing review form
- 20 copies of ALL consents/assents
- 20 copies of protocol summary

**These should be collated into individual packets with 2 of the packets containing the protocol and any publications/presentation information.

Expedited Review:

- 1 copy of protocol
- 1 copy of continuing review form
- 1 copy of ALL consents/assents
- 1 copy of protocol summary
- 1 copy of publications/presentations

***Consent Documents

1) Continuing participant enrollment: Attach one clean copy (no notes, no highlighting, no stamps or no signatures) of the current consent document. This clean copy of the consent document will be stamped and returned to the investigator with the current approval period. *This stamped consent document should be the only form used to consent participants.* All previous versions of this consent document are considered invalid and may not be used to consent participants.
2) Closed to participant enrollment: Attach one copy of the current consent document. Note: A stamped consent document with the new approval period will not be sent to the investigator.

***HIPAA Authorizations and Waivers of Authorization do not expire and, therefore, do not need to be resubmitted to the UMCIRB office.

CLOSURE OF A RESEARCH STUDY

- Each section should be completed regardless of whether this form is being submitted for continuing review or closure of a research study
- No consent documents are necessary.
- A copy of the protocol or protocol summary is not required.

ACTION REQUESTED

☒ Renew—continued participant enrollment
☐ Renew—no additional participant enrollment with follow-up for enrolled participants only, utilizing research related interventions conducted solely for gathering protocol related information
☐ Renew—no additional participant enrollment with long-term follow-up for enrolled participants only, utilizing follow-up interventions considered standard of practice that creates no research related burden for participants
☐ Renew—no additional participant enrollment; data analysis and interpretation only
☐ Terminate—research completed with no additional participant enrollment or collection of follow-up information. Provide rationale for study termination:

Principal Investigator Signature | Print | Date

Unique Identifier: MedFT meets Childhood Obesity and Diabetes

PROTOCOL SUMMARY

Provide a brief, one page description of the research study. All more than minimal risk research studies and research requiring full UMCIRB review must have a separate protocol.

Study Objective

Researchers are hoping to pilot data collection for exploration of patient and family factors associated with quality of life and depressive symptoms with overweight and diabetic children and their families.

Study Design

The study design is a prospective longitudinal cohort study of convenience samples of patients (children) and caregivers seen at the PHWRTC and Diabetes Clinic. The projected number of participants is 100 children diagnosed with obesity, Type 1 Diabetes and Type 2 Diabetes. The process of administering the PedsQL4.0, PHQ-9, and disease specific QOL (either IWQOL or Diabetes QOL) scoring results, entering means into Centricity, and surveys into the database will be done for 12 months.

Target Population

Children ages 5-18 years old and their caregivers will be recruited for participation in research. Participants will be initial patients or existing patients being seen for follow-up appointments at the PHWRTC and Diabetes Clinic. Individuals that speak a language other than English will be excluded from research as well as individuals who are cognitively impaired.

Study Instruments

The Pediatric Quality of Life Inventory 4.0 (PedsQL4.0) is a research tool that provides insight into how children are impacted through their illness experiences (Varni, 1998). Furthermore, this instrument gives clarity as to which dimensions are most difficult in an overweight and/or Diabetic child's life. The choice for a quantitative measure was made due to the need for comparison between the different dimensions of physical, emotional, social, and school functioning. The Cronbach reliability coefficient for the child module is .88 and .90 for the caregiver module. This assessment was also selected because of its age appropriateness for our typical patient (age 2 to 18) and the caregiver module that was also available. The PedsQL4.0 gives clinicians and researchers a foundation for development of interventions by addressing four potential problematic dimensions: physical, emotional, social, and school functioning. Because we, as family therapists, are trained to work from a systemic lens, we believe obesity and Diabetes in childhood is not a product of the child's alone. Childhood obesity and diabetes involves many systems including family, friends, neighborhoods, school, and community. The PedsQL4.0 not only asks the child about their functioning, but also asks the caregiver that accompanies the child to fill out a separate module about their child's functioning, thus giving us insight into the illness experience the whole system is experiencing. Researches will additionally use the Diabetes Quality of Life inventory for caregivers and children with Type 1 and Type 2 Diabetes. Caregivers and children who are obese will use the IWQOL inventory. The Diabetes QOL and the IWQOL allows researchers to look more intensely at the impact of specific diseases (e.g. Diabetes or obesity).

The Patient Healthcare Questionnaire (PHQ-9) was selected to provide a greater understanding of the affect that 'overweight' and/or diabetes has on depression in children seen at the PHWRTC and Diabetes Clinic. The PHQ-9 assesses for depression ranging from mild to severe. The PHQ-9 reliability was tested using a test-retest with a range of scores from .68 to .95. However, the PHQ-9 is only age appropriate for 12 to 18 year old children and their caregivers. Children younger than 12 years will have depression assessed via the social and emotional subscales, only through the PedsQL4.0.

For the PHWRTC caregivers an additional fatigue inventory was added to determine whether caregiver symptoms may be fatigue or depression related.

Methods

The PedsQL4.0 and PHQ-9 will be administered to each new patient and their caregiver upon their initial visit to the Pediatric Health Weight Clinic and Diabetes Clinic. There are different age appropriate PedsQL4.0 and Diabetes QOL module levels for the child dependent on age: young child (5-7 years old), child (8-12 years old), and teen (13-18 years old). Caregivers fill out the same modules with the addition of a toddler module (2-4 years old). In addition to the PedsQL4.0 the PHQ-9 and IWQOL will be given to children 12 years and older. Family caregivers are asked to complete the PedsQL4.0, by assessing their child's quality of life, however the PHQ-9 is completed on the caregiver's perspective of his/her own life. These assessments provide the researchers and providers with a more complete picture of the entire family. Prior to the modules being administered a signed informed consent will be obtained from caregivers and signed assent from children. There is no perceived risk from these tools being administered to children and their caregivers. It will be explained that care is not based upon completion of the research and that participation is voluntary. Caregivers and children will fill out the survey separate from each other. If questions arise while the child or caregiver is taking the survey a member of the research team will be available to provide clarity and facilitate understanding of questions.

Upon completion of the research, Ms Pratt or one of the family therapy interns will score the measures immediately. Results are discussed with the patient at the end of the consultant with the physician. It is important to note that for research purposes this measure is used quantitatively; however, clinically it can be used qualitatively in discussions of results and post-visit implications for children and caregivers.

The results from the caregiver and child surveys are to be placed into a locked file cabinet. They will enter the mean score for physical, psychosocial, and total functioning scores into Centricity on the database used by Pediatrics. After scores are entered into Centricity (an electronic medical record system), the results from the research will be entered into a SPSS database. Each survey is

Unique Identifier: MedFT meets Childhood Obesity and Diabetes

assigned a unique identifier (number) based on date given. Centricity (medical record system) access will be needed for monitoring which patients have received the research.

- Patient follow-up appointments will be tracked (via a flagging tool) in Centricity. Material to be extracted will include changes in Body Mass Index (BMI), comorbidities, weight change, change in nutrition and physical activity behaviors, and amount of visits the patient as been seen at the PHWRTC and Diabetes Clinic.

Assent: To be completed by Pediatric Healthy Weight patients aged 5-17

Primary Investigators: Keeley J. Pratt, MS and Angela L. Lamson, PhD
East Carolina University
150 Rivers Building, Greenville, NC 27834
(317) 902-7233 or (252) 737-1415

You are being asked to take part in a study about your feelings of being overweight and your treatment experience at the Pediatric Healthy Weight Clinic (PHWC). We are interested in learning about your feelings towards yourself. If you agree to join this study, you will be given some paper and pencil forms to complete at your visits at the PHWC. There will also be paper and pencil forms at your follow up appointments. There are no right or wrong answers. We just want you to tell us about your current feelings. If you feel uncomfortable answering any of the questions, please do not fill in the answer to that question, and move on to the next question that you feel comfortable answering. You do not have to take part in this study if you do not want to.

We will provide you with the forms upon your initial visit and your follow up appointments. The paperwork at the initial visit may take up to 10 minutes, and 10 minutes at each of the follow up appointments. However, you may take as long as you like in order to finish. There will be a member of the research team available to answer your questions. If you have a question please ask your parent/caregiver for permission to call Ms Keeley Pratt or another member of the team for help. If you have a lot of worries or concern we will let your parent/caregiver know. Once you are finished with these forms please give them to the member of the team present with you in the room.

I have had this study explained to me in a way that I understand and I have had the chance to ask questions. I agree to take part in this study. If I have questions about the study, I may contact Ms Keeley Pratt at (317) 902-7233 or Dr. Lamson at (252) 737-2042. If I have questions about my rights as a research subject I may contact the Chair of the University and Medical Center Institutional Review Board (UMCIRB) at (252) 744-2914.

Signature of Minor:_____ **Date:**_____

_____ **Date:**_____
Signature of the Parent who consents for their child to participate

_____ **Date:**_____
Signature of Primary Investigator

INFORMED CONSENT: To be completed by the Caregiver of the Pediatric Healthy Weight patient

Primary Investigators: Keeley J. Pratt, MS and Angela L. Lamson, PhD
East Carolina University
150 Rivers Building, Greenville, NC 27834
(252) 864-7711 or (252) 737-1415

Exclusionary Information:
This informed consent can only be signed by persons over the age of 18 who are not cognitively impaired or who reside in an institutional form of housing (juvenile home, prison, residential facility for mental or physical care).

Purpose:

The purpose of this research is to look at quality of life and depressive symptoms in overweight children and their caregivers. The researchers are additionally interested in how quality of life and depressive symptoms change with each visit to the Pediatric Healthy Weight Clinic (PHWC). The research will give future direction in regards to prevention and treatment of overweight/obesity in children.

Process:

As part of your care during your visits to the PHWC you will be asked to complete three surveys. We are asking your permission to also use these surveys in our research. In addition, we are asking you to complete a background information questionnaire for the research project. Research may take up to 10 minutes to complete initially, and most likely 10 minutes at follow up appointments; however, you are welcome to take as long as you would like to finish. There is a child (patient) and caregiver research packet The packets are to be completed independently with out consult from child to caregiver or caregiver to child. There will be a member of the research team available to answer your questions.

Risks:

There are no anticipated physical, psychological, social, legal, professional, or economic risks or discomforts. This study will request your consent for the researchers to administer and collect the research presented to you. Participation will include the time needed to complete the survey. If at any time you become concerned about yourself or your family member who is completing the additional child packet please discontinue use. You may call the primary investigators: Keeley Pratt or Dr. Lamson if you have additional questions or concerns regarding this survey or any aspect of the research.

It is important that you understand that this research study has no connection to the kind, frequency, or ability for you to receive services or treatment at the Pediatric Healthy Weight Clinic(s). Should you decline to participate in this research it will not interfere with you right to receive treatment and care for your child. Your participation in this research project will simply help researchers better understand children and caregivers quality of life and feelings (such as depressive symptoms) while been seen at the PHWC. This research will give researchers valuable information to share about the treatment of overweight in childhood.

The purpose of the information to be gathered for this research study is to better understand quality of life and depressive symptoms in overweight children and their caregivers. The individuals who will use or disclose your identifiable health information for research purposes include Ms. Keeley Pratt. Individuals who will receive your identifiable health information for research purposes include Ms. Pratt and the research team. The type of information accessed for this research study includes children's height, weight, and body mass index measurements over time. The information will be used and disclosed in such a way as to protect your identity as much as possible; however, confidentiality cannot be absolutely

guaranteed. Someone receiving information collected under this Authorization could potentially re-disclose it, and therefore it would no longer be protected under the HIPAA privacy rules (federal rules that govern the use and disclosure of your health information). There is not an expiration date for this Authorization.

Consent to Participate:

I understand that my participation is voluntary. Refusal to further participate will involve no penalty. I understand I may not participate in this study if I do not sign this Authorization form. I may also stop participation at any time or decline any further question that is too difficult to answer. I understand that my name will be give by the Pediatric Healthy Weight Clinic to the primary researchers of this project for follow-up purposes only. I also understand that my name will not be associated in any way to the research findings or data entry. If any questions arise about my rights as a participant, I know I may contact Ms Pratt (317) 902-7233 or Dr. Lamson (252) 737-2042. If I have questions about my rights as a research subject I may contact the Chair of the University and Medical Center Institutional Review Board (UMCIRB) at (252) 744-2914. I know I may revoke (withdraw) this Authorization by submitting a request in writing to Ms. Pratt, 150 Rivers Bldg, Greenville NC 27858. However, the research team will be able to use any and all of the information collected prior to your request to withdraw your Authorization.

I certify that I have read all of the above, asked questions and received answers concerning areas I did not understand, and have received satisfactory answers to these questions. I willingly give my consent for participation.

_____ **Date:**_____
Signature of the Caregiver who consents for their child to participate

_____ **Date:**_____
Signature of Primary Investigator

Appendix B: Dissertation Proposal
Chapter 3: Introduction

For over half of a century obesity has been identified by researchers as an established pediatric condition (Gordon & Hill, 1957). However, today childhood obesity is identified as a nationwide epidemic that impacts children regardless of sex, age, race, and ethnic group (Federal Interagency Forum on Child and Family Statistics, 2007; Hedley et al., 2004; Institute of Medicine, 2005). Through the use of longitudinal data, researchers suggest that as obese children grow older, they are more likely to become obese as adults (Mossberg, 1989; Stark, Adkins, Wolff, & Douglas, 1981). In 2004, 18% of children in the United States (US) were reported to be overweight, this percentage translates to a total of 13,140,000 children, or the entire population of North Carolina and South Carolina combined (Federal Interagency Forum on Child and Family Statistics, 2007; US Census Bureau, 2007). According to the Institute of Medicine (IOM, 2005), approximately nine million U.S. children age six and above are obese, compelling policy makers to rank childhood obesity as a critical public health threat.

The significant and rapid increase in the number of children who are overweight or obese has left researchers scrambling to understand the healthcare outcomes for the 13 million children and their families impacted by this condition. Researchers suggest that 80% of children who are overweight or obese at 10-15 years of age remain obese when reassessed in their mid twenties (Whitaker, Wright, Pepe, Siedel, & Dietz, 1997). With many variables still uncertain, researchers propose that some contextual variables tend to be correlated with higher rates of obesity including age (as it relates to ethnicity), socioeconomic status (SES), and parental constellation (e.g., single parent or two parent) (Golan, Fainaru, & Weizman, 1998; IOM, 2005; DHHS HRSA MCHB, 2005).

Ethnicity

Nationally, the prevalence of childhood obesity is most significant in middle-and high school-aged children and those from ethnic minority populations (Hedley et al., 2004; Ogden, Carroll, & Flegal, 2002, 2008). According to National Health and Nutrition Examination Survey (NHANES) data, non-Hispanic Black children have the highest rate of obesity (22.9%), with Mexican American and non-Hispanic White children having lower prevalence, at 21.1% and 16%, respectively (DHHS HRSA MCHB, 2005; Freedman, Dhan, Serdula, Ogden, & Dietz, 2006; Hedley et al., 2004; Ogden, Carroll, & Flegal, 2002, 2008). Asian children appear to have a similar obesity prevalence as White children (Freedman et al., 2008). Specifically, child populations that have the highest prevalence of obesity include adolescent Mexican American boys (22%) and non-Hispanic Black girls (24%) (Caprio et al., 2008). These differences may be due to multiple complex variables such as interacting with ethnicity, sex, and SES.

Socioeconomic Status

The assessment of SES is often comprised by systemic variables such as family income, caregiver education, and residential proximity. All of these variables appear to be associated with the prevalence of childhood obesity. For instance, family income has been shown to have an inverse relationship with childhood obesity; as income increased, the prevalence of obesity in children decreased (DHHS HRSA MCHB, 2005). SES, income, residential location (i.e., southern regions of the US as compared to other parts of the nation), and caregiver education level are important elements to understanding childhood obesity; however, family factors such as structure must also be considered.

Family Structure

In the National Survey of Children's Health (2003-2004), parental/family structure (e.g., single parent or blended families) was found to be a factor that influenced overweight or obesity in children. For example, children who lived in two parent (biological or adoptive) households were least likely to be overweight (12.2 %) as compared with children who lived with at least one step parent (15.2 %); and children who lived with single mothers (18.9 %) who had the greatest prevalence of overweight (DHHS HRSA MCHB, 2005). Researchers have yet to document why single mothers are more likely to have children who are more overweight than those in dual parent homes. While some speculate that family/parental structures have implications for childhood overweight patterns, others suggest that parental behaviors (e.g., physical activity and food choices) are significantly correlated with children's health (DHHS HRSA MCHB, 2005).

Caregiver Modeling

Caregiver (parental) health-related behaviors are becoming of greater interest among researchers, as childhood obesity moves from a child-focused to a family-focused concern (Epstein, Valoski, Wing, & McCurley, 1994; Golan, Fainaru, Apter, & Weizman, 1998; Golan, Weizman, & Fainaru, 1999; Goldfield, Epstein, Kilanowski, Paluch, & Kogut-Bossler, 2001). Children who have parents who are overweight are found to be at an increased risk of becoming overweight themselves (Temple, Wrotniak, Paluch, Roemmich, & Epstein, 2006). Parent modeled health behaviors or lifestyle habits (e.g., regular exercise and eating patterns) appear to play an integral role in the prevalence of being overweight as a child.

Certain parental modeling behaviors are considered to be protective factors for overweight children including making healthy food choices, exercising habits, and having a

positive body image. For example, children who have at least one parent who exercises regularly are less likely to be overweight. This outcome demonstrates the importance of the parent-modeled behavior of physical activity. Other protective factors related to family exercise, such as SES and safer communities are also associated with obesity rates. Children who have parents with a higher income and live in a safer community tend to exercise more (DHHS HRSA MCHB, 2005). Unfortunately, considering caregivers and contextual variables as part of childhood obesity treatment had not been considered much in the past, that is until the establishment of the 2007 Expert Recommendations.

Expert Committee Recommendations

The report entitled *Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity* (2007) summarizes the findings of the Expert Committee of currently accepted practices for pediatric obesity prevention, assessment, intervention, and treatment (Barlow, 2007). This report synthesizes several innovative elements, such as family involvement, inclusion of multidisciplinary providers, and specific trajectories of treatment of children who are at an unhealthy weight. This is perhaps the only document in existence for all healthcare providers, regardless of their discipline, to utilize in the battle against the obesity epidemic.

The rise in pediatric obesity is forcing treatment programs to adapt to the needs and demands of children and families impacted by this epidemic. One way that childhood obesity programs can be developed, implemented, and assessed is through the lens of C.J. Peek's three-world view (Patterson et al., 2002). The three-world view informs healthcare settings, including pediatric obesity treatment programs, as they face three simultaneous challenges (a) the clinical challenge to provide exceptional patient care; (b) the operational challenge to employ efficient,

well-integrated, and patient-friendly systems of care; and (c) the financial challenge of staying financially feasible and employing health care resources (Patterson et al., 2002). Peek (2002) called these three distinct challenges “world views.” In the three-world view it is important to look at each world in relation to the others, because no one world can function independently from the others, and no one world is considered more important than another. The focus of this dissertation will be on the clinical world of pediatric obesity while still considering how operational and financial worlds inform the PHWRTC’s clinical outcomes.

Dissertation Articles

The purpose of article one within the dissertation is to explore the evolution of pediatric care for obese and overweight children by addressing: 1) terms, recent expert recommendations, and the implementation guide pertaining to pediatric obesity treatment and 2) a structure for synthesizing clinical, operational, and financial practices through the three-world view, discussed further below (Patterson et al., 2002). The purpose of article two is to identify changes in outcomes from initial visits at the PHWRTC to follow-up visits (V1 and V2).Researchers have studied the association between children’s weight and quality of life, severity of depression, physical activity and nutrition indicators, as well as health status (including BMI and blood pressure), but limited information exists that describes longitudinal interventions and outcomes especially comparing the child’s perspective to that of their caregiver’s. In an attempt to generate long-term, successful interventions, studies must be done to further explore program interventions and outcome data that address biopsychosocial aspects of being overweight. The focus for these researchers is to more fully understand how patients are affected by obesity; via comprehensive assessments deemed valid for children and their families. Article two of the dissertation will offer an assessment of variables that may be related to or predictive of the

variability in changes from initial visits to follow-up visits. Thus the following research questions are proposed:

1. What are the baseline characteristics of the children and their caregivers in terms of age, ethnicity, sex, caregiver relationship to the children, QOL total and scale scores, QOL discrepancy between child and caregiver, depression levels of child (adolescent) and caregiver, health status (including BMI, BP, nutrition behaviors, and physical activity), and readiness for change?
2. At baseline, what are the relationships between (1) QOL, BMI (z-score), physical activity; (2) QOL child and caregiver discrepancy scores and child QOL; (3) QOL and PHQ9 scores; (4) QOL and readiness to change; (5) nutrition behaviors and BMI; and (6) nutritional status and QOL, and are these relationships related to the child's age, sex, or ethnicity?
3. Are there changes in QOL, BMI (z-score), PHQ9, nutrition behaviors, and physical activity from V1 (initial visit) to V2 (first follow-up visit) to V3 (second follow-up visit) for the total group?
4. Are the V1 – V2, and V1 – V2 – V3 changes in QOL, BMI (z-score), PHQ9, exercise frequency, and nutrition behaviors related to (1) child's age at V1; (2) child's ethnicity; (3) time between visits; (3) V1 BMI category; (4) readiness for change at V1 or V2; (5) V1 family structure (one or two caregivers); (6) level of discrepancy between child and caregiver QOL at V1 or V2; or (7) sex of the child?
5. Are there V1 variables related to V2 attrition, and V1 and V2 variables related to V3 attrition?

Chapter 4: Literature Review

In 2005, the American Medical Association (AMA), Health Resources and Services Administration (HRSA), and Centers for Disease Control and Prevention (CDC) brought together an expert committee including representatives from the areas of medicine, mental health, and epidemiology to develop recommendations for the care of overweight and obese children (Barlow, 2007). The report entitled *Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity* (2007), summarizes the findings of the Expert Committee for currently accepted practices of pediatric obesity prevention, assessment, intervention, and treatment. A concurrent publication by the National Initiative for Children's Healthcare Quality (NICHQ) entitled *An Implementation Guide from the Childhood Obesity Action Network* offers a combination of the expert recommendations and real-world practice tools identified by primary care groups who have developed obesity care strategies (NICHQ, 2007). Thus, the implementation guide offers suggestions and tools for practical application of the expert recommendations. The following paragraph outlines the changes in terminology related to childhood obesity based on the Expert Recommendations followed by a thorough description of the four stages of treatment.

The terminology for defining childhood obesity is different in the Expert Recommendations compared to previous pediatric obesity literature. Children's weight is categorized by age and gender-specific Body Mass variables (BMI). There are four weight categories for children: underweight ($< 5^{th}$ percentile), healthy weight (5^{th} - $<85^{th}$ percentile), overweight (85^{th} - $<95^{th}$ percentile) and obese ($\geq 95^{th}$ percentile). The term, "at-risk for overweight" is no longer recognized as an appropriate descriptor. Using this new terminology, the focus for this dissertation will be with children considered *overweight* or *obese*. Furthermore,

the criteria set forth by the Expert Committee Recommendations will be included in the dissertation as a basis for clarifying current clinical and research practices that pertain to article one of the dissertation, and as the foundation for the research outcomes described in article two of the dissertation.

Recommended Stages of Childhood Obesity Treatment

Prevention strategies for all children are recommended via four stages of childhood obesity treatment: 1) prevention plus; 2) structured weight management; 3) comprehensive, multidisciplinary intervention, and 4) tertiary care intervention (Barlow, 2007). A prevention or stage one "prevention plus" visit most commonly takes place at a child's primary care office during a yearly well care visit. At a stage one well care visit, the following are to be included by the healthcare provider: a plot of body mass index (BMI); a weight category identification (i.e., underweight <5 percentile, healthy weight 5-84 percentile, overweight 85-94 percentile, obese 95-98 percentile, and ≥ 99 percentile); blood pressure measurement; a family focused medical history; a focused review of body systems; a thorough medical physical examination including appropriate laboratory tests; and a consistent evidence-based messages for physical activity and nutrition. At stage one, providers should also assess beyond dietary and physical activity behaviors by looking at the child's attitude, including self-perceptions or concerns about weight, readiness to change (i.e., child and caregiver likelihood of adopting new healthy lifestyle habits), successes, barriers, and challenges (Barlow, 2007; NICHQ, 2007; Spear et al., 2007). Finally, it is recommended that the physician follow certain communication strategies (i.e., empathize, elicit, and provide) to improve the effectiveness of counseling.

At stage two, structured weight management visits take place at a primary care office with the added support of a healthcare provider who has specific training in weight management.

Visits provide an increase in structure and support, specifically toward setting physical activity and nutritional goals and creating rewards. Stage two visits ideally occur on a monthly basis either with the child seen individually or as part of a group visit.

In stage three, a comprehensive multidisciplinary intervention goes beyond stage two by employing multidisciplinary childhood obesity treatment and a structured behavioral program (e.g., negotiating and reinforcing positive healthy behaviors). Ideally, families are seen weekly for 8-12 weeks with additional follow-up services.

At stage four, a tertiary care intervention is aimed at severely obese youth by utilizing treatments such as medications (e.g., Sibutramine or Orlistat), very-low calorie diets, and/or weight control surgery (i.e., Gastric Bypass or Lap-band) in addition to behavioral treatment. Thus, obesity treatment can occur in traditional "one on one" medical encounters in a primary care context or evolve to multidisciplinary and collaborative care. The history and evolution of these diverse treatment modalities are described below.

Trajectory of Pediatric Obesity Treatment

Traditional Treatment

Initially, the traditional treatment of pediatric obesity was done in a primary care context where children and their families likely had encounters with a single healthcare provider (i.e., a pediatrician) (Gordon & Hill, 1957) and probably had limited access to other healthcare professionals, such as a nutritionist/dietician or a behavioral healthcare provider. A traditional encounter would focus primarily on the biological symptoms presented and rarely focus on behavioral changes. Any additional services would be coordinated, but not typically co-located (see Table 1 on page 61). That is, information may be exchanged from one treatment setting to another via letter, telephone, or what is most commonly in this age, through electronic

transactions. In most traditional treatment venues, the child was considered the identified patient and parents were often excluded from goal setting or treatment plans.

However, later in the second half of the twentieth century family-centered care began to emerge (AAP, 2007). Specifically, since at least 1976 obesity has been viewed as a familial disorder (Garn & Clark, 1976) and family-centered treatment for childhood obesity has become a documented treatment approach (Epstein, Rocco, Roemmich, & Beecher, 2007). Edmunds and colleagues (2001) asserted that the family has proven to be the most appropriate environment for the treatment and prevention of childhood obesity. Providers who use family-centered childhood obesity treatment tend to view the family as the identified patient and thus include them in goal setting and treatment plans.

Family-centered care values are present in the Institute of Medicine's (IOM) report *Crossing the Quality Chasm: A New Health System for the 21st Century* (IOM, 2001). Specifically, "patient-centered care focuses on accommodating family and friends on whom patients may rely, involving them as appropriate in decision making, supporting them as caregivers, making them welcome and comfortable in the care delivery setting, and recognizing their needs and contributions" (p. 50). Family-centered care is alluded to for all healthcare providers in the recent obesity care recommendations for all four of the stages of care. Overweight and obese children and their families have complex needs that demand family-centered care, and if obesity becomes a long term concern, the family's needs may require a multidisciplinary and collaborative group of providers who can work on their behalf.

A Shift to Multidisciplinary, Collaborative Care

In the pediatric literature, multidisciplinary care for obesity (in nonsurgical programs) was not explicitly stated as an essential element until the 2007 recommendations that now lists

health professionals such as dieticians, psychologists, and health educators as helpful in childhood obesity treatment from structured weight management (stage two) encounters in a primary care context through tertiary care intervention (stage four) (Barlow, 2007; NICHQ, 2007). Although research has provided evidence for using a multidisciplinary team (Epstein et al., 2007; Fickel, Parker, & Yano, 2007; Flodmark, Lissau, Moreno, Pietrobelli, & Widhalm, 2004; Hunter & Larrieu, 1997), previous recommendations from the American Academy of Pediatrics (AAP) and Agency for Healthcare Research Quality (AHRQ) in the United States did not emphasize multidisciplinary care for children. For example, Plourde (2006) contended, "mild uncomplicated obesity can usually be managed in primary physicians' offices. [Only] patients presenting with obesity-associated comorbidity require more intensive multidisciplinary treatment" (p. 327). Therefore, based on the most recent expert recommendations, implementation guide, and authors such as Plourde, it appears that only after a child has failed at weight-loss or maintenance in primary care that multidisciplinary providers are pursued. One significant concern with this perspective is that when children and families finally come to receive multidisciplinary healthcare services, they may already be viewed as "unsuccessful" or "noncompliant" from the first intervention attempted with their primary care provider.

Interestingly, an international perspective on childhood obesity treatment per the European Childhood Obesity Group is that multidisciplinary programs including family involvement are needed because treatments that include diet, exercise, behavioral therapy, surgery, and medication fail to be effective in isolation of one another; instead treatment needs to be "supporting and long lasting" (Flodmark et al., 2004, p. 1192), including psychological factors as an essential element in treatment as children are maturing (Flodmark et al., 2004). In fact, the NIH and the IOM suggest that all adult obesity treatment programs (i.e., specifically for

surgical treatment) involve multidisciplinary (i.e., behavioral, nutrition, and exercise) providers (Hunter & Larrieu, 1997). The need for involvement of providers from different disciplines in order to treat pediatric obesity is being established, yet there is no clear method for how multidisciplinary providers would work together, communicate, and deliver services.

It is important for healthcare professionals to clarify that collaborative care means something different than just communication among various providers (which some label as collaboration). Collaborative care is the explicit partnering of behavioral health and medical providers in the care of patients (Blount, 2007). Unfortunately, this distinction is not reflected in the current literature and researchers often use the following terms interchangeably: collaboration, collaborative care, and multidisciplinary care. Establishing a unified or standard definition for these terms would assist healthcare providers, researchers, and policy makers in constructing and analyzing best practices and conducting research in childhood obesity treatment programs (see Table 1 on page 61).

Providers may represent different areas of healthcare expertise, but the way they communicate with one another, release and share information, and provide care plans is indicative of the degree to which multidisciplinary treatment is provided (National Initiative for Health Care Management, 2005). Ginsburg (2008) reviewed four dimensions that one should consider when determining the level of collaboration at a co-located pediatric practice: (a) organizational characteristics (including business arrangements such as contracts, agreements, and administrative and financial services), (b) responsibility for patients, (c) coordination mechanisms, and (d) data systems and policies.

Providers may have different expectations about how collaborative care is achieved or sustained. In a collaborative co-located setting, the responsibility for a patient is shared among

providers (“our” patient) (Fickel et al., 2007), whereas in a less collaborative setting providers may feel as though they are assisting with another provider’s patient (“their” patient) (Ginsburg, 2008). Coordinated mechanisms involve levels of patient care and communication between providers (e.g., referrals, case reviews, and treatment plans) (Ginsburg, 2008). Data system policies vary in how shared electronic records and data are maintained (Ginsburg, 2008). It is important to note that the recent expert recommendations do not address how collaboration should occur at the various stages of obesity treatment, nor do the recommendations outline criteria for communication among the multidisciplinary team of providers in levels two through four.

Integrated Care

One intense form of collaborative care is known as integrated care. Integrated care is collaborative care that addresses the biopsychosocial symptoms of patients. Care is highly coordinated between medical and mental health providers, which can be seen through shared treatment plans (Patterson et al., 2002). What separates integrated care from collaborative care is the appearance of the “unified provider.” Integrated care involves at least one medical and behavioral health provider incorporated into a patient’s treatment plan (Blount, 2003, see Table 1). Often in an integrated care setting a medical and behavioral health provider will provide side-by-side services for a patient (Patterson et al., 2002). Integrated care may involve more than a medical and behavioral health provider; as is the case with childhood obesity where often a physical therapist, case manager, and nutritionist or dietician are included as well. In an integrated care consult, a physician and behavioral health professional may see a patient together in the same physical space at the same time.

However, there are roadblocks to initiating integrated care in a healthcare system because of the lack of clear and effective models for childhood obesity treatment and financial feasibility (Hunter & Larrieu, 1997). The lack of formal guidelines and standardized evaluation for childhood obesity programs is influencing some leaders in the field to advocate for an accreditation process similar to that in academia and hospitals for adult weight-loss programs (Stern et al., 1995). No specific call has been made for an integrated care model to become the standard for childhood obesity.

Caprio (2006) observed that the most effective obesity treatment programs have been carried out in academic centers via an approach combining nutrition, behavior modification, physical activity, and parent involvement (Caprio, 2006). However, such treatment approaches have yet to be translated into the primary care setting. Caprio also stated that successfully treating obesity "… will require a major shift in pediatric care that builds on the findings of these academic centers regarding structured intervention programs" (p. 213). Academic centers have been leading the way in the evolution of pediatric obesity services, in part because of funding, access to free or affordable student services, and the close proximity of diverse healthcare providers. As Caprio pointed out, it will be essential to make such programs and services transferable to a variety of settings and patients beyond academic environments. Until clear and effective models of collaborative, multidisciplinary, and family-centered treatment are established or sustainable, it will be difficult to capture what is happening in healthcare settings with regard to childhood obesity (e.g., what patients and families are experiencing at encounters, what a team is providing and how, and holding team members and childhood obesity programs accountable for quality treatment).

It is clear that settings will demand different levels of collaboration, and for some settings integrated care may not be realistic. However, in order to explore if such care may be feasible, the healthcare setting needs to be assessed according to its clinical, operational, and financial components. One way to assess these components in each setting is by applying the three-world view of C.J. Peek (Patterson et al, 2002). Providers working with specific child populations, such as those who are at an unhealthy weight, may benefit from a structure such as Peek's three-world view to integrate the national recommendations and guidelines with real world clinical, operational, and financial procedures.

The Three-world View & Childhood Obesity

The clinical, operational, and financial worlds all have their own respective internal logic and language (Patterson et al., 2002). For example, the focus in the clinical world is on treatment plans and interventions for patients and families with an emphasis on quality, health outcomes, and goals. "Goals in the clinical world are quality and elegance" (Patterson et al., p. 35). In the operational world, services focus on "the operational systems needed to produce services, with the goals centering on efficiency and facility" (e.g., patient scheduling and flow) (p. 35). The financial world pertains to "utilizing resources and value with an emphasis on business goals and process and accounting" (p. 35). "The goal for the financial world is having the right price and good value" (p. 35). To be a successful program, actions and designs must satisfy all three worlds (Patterson et al.).

The Clinical World of Childhood Obesity

Regardless of the stage of treatment (i.e., prevention to tertiary care), the childhood obesity clinical world is based on provider and patient interaction and thus, the first factor to consider is the provider-patient relationship. Inherent in the dichotomy of the provider-patient

relationship is the patient's past and present relationships and experiences (either negative or positive) with healthcare providers, teams, and settings. Therefore, in the clinical world it is essential to explore the potentially negative experiences that patients may have had in other healthcare contexts, specifically around weight bias and stigmatization from providers. Recently the journal *Obesity* (November, 2008) devoted an entire issue to weight bias, with six articles focusing on youth. Children are specifically identified as being vulnerable to the effects of weight bias (Puhl & Latner, 2007). Unfortunately, there are only a few researchers who have published on weight bias across the lifespan (Puhl & Latner, 2008), making it difficult to predict what biases a family (and the individuals that make up a family) has experienced prior to current treatment.

Parents of obese children report feeling blamed for their child's weight and dismissed by their healthcare providers (Edmunds, 2005). Weight bias is documented among physicians (Campbell, Engel, Timperio, Cooper, & Crawford, 2000; Hebl & Xu, 2001; Kristeller & Hoerr, 1997; Maiman, Wang, Becker, Finlay, & Simonson, 1979; Price, Desmond, Krol, Snyder, & O'Connell, 1987), medical students (Blumberg & Mellis, 1980; Keane, 1990; Wigton & McGaghie, 2001), dieticians (Berryman, Dubale, Manchester, & Mittelstaedt, 2006; McArthur & Ross, 1997; Oberrieder, Walker, Monroe, & Adeyanju, 1995), nurses (Bagley, Conklin, Isherwood, Pechiulis, & Watson, 1989; Hoppe & Ogden, 1997; Maroney & Golub, 1992), and psychologists (Davis-Coelho, Waltz, & Davis-Coelho, 2000; Hassel, Amici, Thurston, & Gorsuch, 2001). In their initial interactions, healthcare providers' sensitivity with patients may assist in building a trusting patient-provider relationship whereby care is well received at any stage of treatment.

Part of emphasizing the patient-provider relationship is demonstrating the need for all family members to be part of treatment (i.e., family-centered). There are inherent benefits to treating a family rather than a child in isolation. For example, Epstein, Rocco, Roemmich and Beecher (2007) noted that, "Obesity runs in families, it has been hypothesized that targeting eating and activity change in the child and parent, along with teaching parents behavioral skills to facilitate child behavior changes, could mobilize family resources to improve the efficacy of childhood obesity treatments" (p. 381). The benefits of treating children and family members simultaneously may also create positive relationships between the child and parents' weight change (Wrotniak, Epstein, Paluch, & Roemmich, 2004, 2005), including parental nutrition and physical activity behaviors. The working group on National Heart Lung and Blood Institute (NHLBI) Future Research Directions in Childhood Obesity Prevention and Treatment (2007) highlighted three main recommendations for behavioral and lifestyle interventions to treat children who are obese: "1) identify family dynamics which predict success of certain interventions and changes in family dynamics and relationships that are associated with favorable treatment outcomes; 2) identify utility of and methods for promoting self-monitoring of target behaviors by parents and children; and 3) investigate strategies to effectively recruit families into family-centered interventions" (NHLBI, 2007, p. 7).

Family-behavioral treatments have been documented to be an effective clinical strategy for weight-loss in children (Edmonds et al., 2001; Young, Northern, Lister, Drummond, & O'Brien, 2007), and are listed in the expert recommendations for stages three and four (structured comprehensive multidisciplinary intervention and tertiary care intervention). In a recent meta-analysis of 16 studies, interventions that include a family-behavioral component produced larger effect sizes than interventions without a family-behavioral component (Young et

al., 2007). Epstein et al. (1994) found that behavioral family-centered treatment, which emphasizes reinforcement for child and parent behavior changes and weight loss, may have lasting effects into young adulthood. Issues such as readiness to change, parenting skills (e.g., use of praise, rewards, and discipline), and healthy role-modeling are important components in family-centered childhood obesity treatment (Connolly, Gargiula, & Reeve, 2002).

Although there is extensive literature about childhood obesity clinical interventions (whether they be diet, activity, or behavior based), only some examine the degree of family involvement (specifically through parents) with the provider or appear to be family-centered and involve multidisciplinary members in treatment teams, such as nutritionists, physicians, psychologists, and exercise physiologists. Additionally, researchers have not offered outcomes documenting the effect of treating specific familial psychosocial issues such as depression and low self-esteem longitudinally over time in conjunction with weight management services, such as nutrition and physical activity interventions. What appears to be lacking in the current clinical world is a way to organize team collaboration in an operational way to specifically meet the needs of children and families struggling with obesity.

The Operational World of Childhood Obesity

Inherent in the settings and the intensity of a clinical intervention are the operations and organization in which the intervention is delivered. Patients spend minimal amounts of time in medical systems; instead they spend the majority of their time in environments that have unhealthy food choices and promote inactivity (Dietz, 2004). For example, Dietz (2004) asserted "our one-on-one physician-provider relationship model is ill-suited to a problem that affects 15% of patients and engages so many environmental factors" (p. 16). Researchers suggest that pediatricians feel inadequately prepared to address childhood obesity (O'Brien, Holubkov, &

Reis, 2004; Story et al., 2002; Trowbridge, Sofka, Holt, & Barlow, 2002). Physicians, as the primary provider, continue to oversee most patient care, although they are not necessarily trained to address all the complexities present with families who are seeking help for a child that is struggling with weight. Ultimately this may lead to reduced productivity, a key marker in the operational world. Therefore, the involvement of other healthcare providers becomes even more important (Dietz, 2004). Of additional importance is the operational support for financial success. Charles Homer, CEO of NICHQ asserted, "Having support at the top is critical, a CEO or department head who is convinced that this (childhood obesity) is a serious issue that (it) deserves extra attention and resources" (Homer, 2008, p. 37).

The operational world not only encompasses ideal training and identification of appropriate providers to tackle childhood obesity, it also includes healthcare policy. Healthcare policy is essential because policies may assist or thwart the healthcare system's ability to address obesity, specifically through multifaceted interventions (Homer & Simpson, 2007). In a report given to the second National Childhood Obesity Congress, Simpson et al. (2008) pointed out that most policy attention in childhood obesity is focused on schools and the built environment rather than healthcare (Simpson, Alendy, Gunther Murphy, & Network, 2008). Simpson et al. highlight the particular areas of healthcare policy that should be addressed; "research and funding priorities need to identify effective prevention and treatment approaches; training and competency of healthcare professionals in preventing, identifying and treating affected children and families; inclusion of obesity-related services in benefit coverage; incentives for providers and health plans to address the issue; support of innovations, including quality improvement; and the role of health information technology (decision-support systems and obesity registries)"

(2008, p. 2). Healthcare policy, productivity, and administrative tasks are also dependent upon financial feasibility.

The Financial World of Childhood Obesity

The financial world in collaboration with the clinical and operational worlds has apparent challenges. Policy leaders state that a healthcare system change is needed to "Engage payers and employers in improvement efforts, identify and address financial barriers to better care, and engage pediatric councils that work with insurers on coverage and reimbursement" (NICHQ & Blue Cross Blue Shield of Massachusetts, p. 1). Homer suggested "There is a long-standing and widely held belief that there are significant barriers to healthcare reimbursement. Some public (and private) plan directors have taken it upon themselves to reeducate their physicians; even in states where there are few barriers to coverage, this belief still stands" (Homer, 2008, p. 37).

In 2004, the United States Department of Health and Human Services removed language from the Medicare Coverage Issues Manual that indicated obesity was not an illness (US Department of Health and Human Services, 2004). This decision now allows Medicaid coverage for evidence-based obesity treatments to be developed (Rosenbaum, Wilensky, Cox, & Wright, 2005). Medicaid, covering 22.2 million children (or 28.2% of all children), is the largest single source of health insurance for children in the United States, especially for minority children and those of low socioeconomic status (SES) (AAP, 2008; Rosenbaum et al., 2005), two groups with a high prevalence of obesity. Medicaid provides coverage for children until they are 21 years old through the Early Periodic Screening Diagnosis and Testing (EPSDT) program (Wilensky et al., 2006). The EPSDT program (unlike all private insurance) focuses on early intervention, preventive care, and broad coverage; all of which are necessary for care of children who are overweight or obese (Wilensky et al., 2006).

A review conducted by George Washington University entitled *Strategies for Improving Access to Comprehensive Obesity Prevention and Treatment Services for Medicaid-Enrolled Children*, looks at how state Medicaid EPSDT programs are promoting best-practice standards in obesity related services (Wilensky et al., 2006). The researchers found that state EPSDT standards do not typically focus on obesity related activities. Additionally, Medicaid managed care contracts generally do not highlight obesity prevention and treatment strategies in reference to EPSDT standards or performance measurement requirements (Wilensky et al.). This seems to suggest that obesity programs (preventive or treatment) are not encouraged, nor are healthcare providers being held accountable for administering them.

However, "a review of state EPSDT billing, coding, and payment practices underscores that existing billing codes permit coverage to all procedures and interventions essential to high quality obesity-preventive pediatric practice" (Wilensky et al., p. 4). Specific challenges may include limiting the number of payable/reimbursable visits, coverage based on coded services for same day visits, and operating under billing for certain overweight and obesity procedures (Wilensky et al., 2006). It appears that one common challenge in the financial world is that often times providers don't know how to code in order to be reimbursed for obesity and its related comorbidities (Homer, 2008).

Wilensky et al. (2006) affirm that "Overall, Medicaid is well-equipped to tackle the rising obesity problem; the coverage is available but several obstacles exist" (p. 4). First, they recommend that states should clarify the application of obesity prevention and treatment recommendations as part of the EPSDT benefit for children and adolescents. This recommendation would

> "… ensure that covered services are translated into best practices, state agencies could take the extra step of disseminating and ensuring use of practice guidelines then information relating to obesity-services could be included in fee-for-service guidance as well as managed care contracts" (p. 4).

Second, proper coding and payment procedures must be clarified for obesity prevention and treatment services. "States could develop billing guidelines that support appropriate billing coding and could examine other payment standards and limitations that may need to be adjusted in cases involving obesity treatment and prevention (e.g., adjusting maximum visits or duration limits)" (p. 5).

Third, obesity prevention and treatment services should be bundled into a single package. In this model all "already-covered" Medicaid services (including behavioral health) would be bundled into an obesity prevention and treatment payment system that would include guidelines about care, instructions on billing and coding, and level of reimbursement (Wilensky et al., 2006). Billing and coding for obesity treatment can be difficult if interventions are not well known or evidence-based. Thus, evidence-based, child-focused interventions (e.g., behavioral, family, BPS interventions) using standardized procedures may offer a greater likelihood for reimbursement.

Evidence-based, Child-Focused Interventions

Behavioral interventions have been seen as the "first line treatment" for weight loss since at least 1987 (Mellin, Slinkard, & Irwin, 1987). In 2008, Whitlock, O'Connor, Williams, Beil, and Lutz published (for the Agency for Healthcare Research and Quality) the evidence from existing systematic reviews containing behavioral, pharmacological, and surgical weight management interventions for overweight and/or obese children and adolescents in clinical and

nonclinical community settings. Whitlock et al. defined behavioral interventions as including the modification of food consumption (i.e., limiting high-calorie-low nutrient foods and beverages), increasing physical activity, frequent involvement of the child's family members, and optimally cognitive and behavioral therapy. Stated simply, behavioral interventions are currently delineated as physical activity, dietary, family, and behavioral treatment.

Whitlock et al. found that children ages 5-18 and who are classified as obese (not just overweight) are primarily targeted for weight-related interventions. These researchers identified 18 fair or good quality trials, including behavioral weight management interventions (totaling 1,794 obese children). Short-term outcomes in weight change, according to this systematic review, suggest that school-based or specialty-care settings result in small to moderate short term improvements, as opposed to primary care contexts. Absolute weight change from behavioral based interventions varied by setting and treatment intensity. However, behavioral interventions showed significant variability, making it difficult to conclude that specific components (e.g., physical activity or nutrition) were "successful" (Whitlock et al., 2008). The greatest treatment effects were seen in research with high-intensity residential and specialty healthcare treatment settings rather than at schools, primary care, or Internet-based programs (Whitlock et al., 2008).

Because each member of a family is impacted differently by illness and disease, it is important for healthcare providers to include a comprehensive assessment of health to be able to draw evidence toward behavioral interventions. One way to accomplish this is to utilize inventories that go beyond the biomedical diagnoses by addressing biological, psychological, and social (BPS) issues (i.e., fatigue or depression) for the identified patient (the child) and also assess the different family members' perspectives on BPS issues present in the patient and the family.

Introduction to Article Two

Integrated care, including family-centered and behavioral treatments, need to be followed longitudinally in order to give an accurate picture of what is happening biologically, psychologically, and socially for patients who are overweight or obese and their families. Because integrated care engages providers that represent multiple areas of expertise, BPS issues can be identified by a provider trained in their respective disciplines (i.e., biological-medical provider and nutritionist, psychological-therapist or mental health provider, and social-nutritionist and therapist). In order to seek out longitudinal changes through integrated care treatment, we developed a protocol for assessing BPS indicators for overweight or obese children and caregivers. For the purpose of this study, we are particularly curious about changes from baseline variables in QOL, depression severity, and health status variables over time. Overall, the researchers hope to generate a comprehensive and longitudinal picture of how obesity is affecting children and their caregivers.

Biopsychosocial Approach

George Engel developed the biopsychosocial (BPS) approach in 1977 to explore health as an interplay of biological, psychological, and social systems (Engel, 1977). For example, being overweight or obese has several physical implications (e.g., trouble sleeping) that might also be complicated by psychological symptoms (e.g., depression) or social concerns (e.g., bullying). According to Engel, a diagnosis that begins at the subatomic level has systemic ramifications up through societal and cultural levels of interaction.

A formal assessment of quality of life is one method to comprehensively assess how weight may impact a child from a BPS approach. Numerous researchers have used quality of life (QOL) inventories, particularly the PedsQL4.0© (Chan, Mangione-Smith, Burwinkle, Rosen, &

Varni, 2005; Varni, 1999, 2001, 2002, 2003). The PedsQL inventory is used to assess physical, emotional, social, and school functioning, thus providing physical and psychosocial outcomes all in one tool. The domains measured by the PedsQL inventory appear to be comparable to the systems described in Engel's BPS model (Engel, 1977); the biological system relates to the physical domain, the psychological system to the emotional domain, and the social system to the social and school domains.

The relationship between weight and QOL in children has produced inconsistent findings. For example, some researchers have concluded that there is not an impaired quality life for children at an increased weight (Janicke, 2007). However, other researchers have found a relationship between being overweight and decreased quality of life in children and adolescents (Ravens-Sieberer, Redegeld, & Bullinger, 2001; Schwimmer, Burwinkle, & Varni, 2003; Swallen, Reither, Haas, & Meier, 2005). For example, Schwimmer et al. (2003) found that obese children are 5.5 times more likely than healthy children to have impaired QOL, making QOL for an obese child similar to that of a child diagnosed with cancer (Schwimmer et al., 2003). Quality of life appears to be inversely related to weight. As a child's weight increases, her quality of life decreases, so the most overweight children have the most significantly impaired QOL (Williams, Wake, Hesketh, Maher, & Waters, 2005; Zeller, Roehrig, Modi, Daniels, & Inge, 2006).

Some researchers contend that contextual variables further complicate QOL as it pertains to obesity. Ogden et al. (2002) indicated that sex and race play a significant role in quality of life for overweight and obese adolescents. Specifically, in regard to sex differences and QOL, overweight or obese boys report higher physical functioning (Janicke, 2007), while girls report lower social functioning (Zeller et al., 2006). Furthermore, race was found to be an indicator of low QOL scores with African American obese girls. Overall, across all races surveyed,

impairments in physical functioning are more frequently reported than those of emotional, social, or school functioning (Pinhas-Hamiel et al., 2006; Swallen et al., 2005).

Interestingly, other researchers have found no significant association between weight and QOL (Janicke, 2007). The apparent inconsistency in QOL findings has prompted researchers to include additional psychological assessments (e.g., the PHQ-9 (Pfizer, 2000) to enhance the exploration of the relationship between systems (biological, psychological, and social) and QOL. The biological, psychological and social comorbidities are detailed below for children who are overweight or obese.

Biological

The medical literature has documented biological comorbidities of childhood obesity including type-2 diabetes, heart disease, high cholesterol, hypertension, early puberty, enuresis, polycystic ovarian syndrome, and trouble sleeping/sleep apnea (DHHS HRSA MCHB, 2005; Dietz, 1998; Kiess et al., 2001, Institute of Medicine, 2005). If the Expert Committee Recommendations on dietary assessment and physical activity are not adhered to comorbidities can occur. It is recommended that all children regardless of what stage of treatment they are in (prevention through tertiary care) get at least 60 minutes of physical activity a day (Barlow, 2007). Physical activity includes active play, which should be supervised for young children (Barlow, 2007). In regards to nutritional deficiencies, research indicates that children are least likely to consume proper servings of foods from the fruit and vegetables groups, as compared to other food groups (Baranowski, Smith, Hearn, et al., 2005). Additionally, children should reduce their intake of sugared beverages in order to avoid increased calories (Barlow, 2007). Currently, soft drinks are the sixth leading food-source of energy among all children and leading source for adolescents (Murphy, Douglas, Latulippe, Barr, Johnson, & Frye, 2005).

These diagnoses and/or the lack of adherence to dietary and physical activity recommendations/guidelines add complexity to assessment of and treatment for overweight children. To further complicate matters, children and families are expected to meet with multiple providers and follow treatment plans that are grounded in negative outcomes from sleep studies, fasting glucose levels, cholesterol and triglyceride tests, and perhaps most importantly family medical history. Impaired physical functioning may also be related to impaired functioning or quality of life in psychological or social areas.

The biological context, as measured by the PedsQL, encompasses overweight children's physical functioning. Specifically, the assessment of physical functioning includes assessment of body aches, low energy, hygiene, walking, running, and sports or activity. Physically, the QOL assessment helps the researcher to identify key specific activities that may be impaired in overweight or obese children. Identification of such activities may lend treatment teams to develop specific treatment plans that are sensitive to each child's physical abilities, thus setting them up for success both physically and psychosocially.

Psychological

There is little current research documenting the psychiatric problems in children or their families seeking treatment for obesity. Epstein, Valoski, Wing, & McCurley (1994) completed a ten-year follow-up study of family-centered treatment for childhood obesity and found the most prevalent psychiatric problem is depression (Epstein, Valoski, Wing, and McCurley, 1994). In a sample of obese children entering treatment, it was found that 29% met or exceeded clinical levels for psychosocial problems on the Child Behavior Checklist (Achenback, 1991), specifically anxiety and depression. In another sample of obese adolescents presenting for Bariatric surgery, 30% met criteria for clinically significant depressive symptoms (Zeller et al.,

2006). Obese or overweight adolescents who did not live in two parent homes were more likely to be depressed, have low self-esteem, and have poorer school functioning (Swallen et al., 2005). As previously stated, the effect of treating specific familial psychological issues such as depression and low self-esteem over time in conjunction with behavioral nutrition and physical activity interventions is lacking in the literature.

Researchers indicate that children who are obese have increased likelihood for psychological problems that may persist into adulthood as compared to children who are not obese (Epstein, Paluch, Gordy, Saelens, & Ernst, 2000). Psychological impairments include poor self-esteem, low self-worth, depression, loneliness, poor self image, auto-aggression, suicide, drug and alcohol addiction, bulimia, binge eating, and smoking (DHHS HRSA MCHB, 2005; Hoot & Lynn-Garbe, 2005; Kiess et al., 2001; IOM, 2005; Speiser et al., 2005). Due to the lack of longitudinal data, it is unclear whether specific psychological issues (e.g., depression and/or anxiety) persist from youth to adulthood, influence quality of life over time.

The psychological context as measured by the PedsQL, encompasses overweight children's emotional functioning. Emotions that are assessed, include feeling afraid, sad, worried, and angry. Psychologically, the QOL assessment helps the researcher to identify key emotions that may be impacting multiple health-related areas of a child's life such as emotional eating or how these concerns may be impacting a child's social world.

Social

According to Edmunds and colleagues (2001) the social implications for children who are overweight are evident in children at six years of age, when children begin to understand societal messages that being overweight is not desirable (Edmunds, Waters, & Elliott, 2001). Not surprisingly, children who are overweight are more likely to be at risk for peer victimization such

as teasing (Griffiths, Wolke, Page, Horwood, & Team, 2006; Janssen, Craig, Boyce, & Pickett, 2004; Latner, & Stunkard, 2003). Additional social issues for children who are obese include problems associated with school (e.g., performance or poor school attendance), relational issues (e.g., with family and friends), social isolation, promiscuity, and bullying (Janssen et al., 2004), Peer perceptions of children who are obese includes characteristics such as selfishness, poor academic success, and lower intelligence (Epstein, Roemmich, & Raynor, 2001). The BPS symptomatology and comorbidities accompanying childhood obesity warrants new treatment modalities that include a multidisciplinary and biopsychosocial approach.

The social context as measured by the PedsQL, encompasses overweight children's functioning in relationships with their friends, families, and peers at school. In addition, the social area includes bullying, teasing, and social isolation. Socially, the QOL assessment helps the researcher to identify child and caregiver risks, as well as discrepancies between child and caregiver interpretations (e.g., incongruence between child and caregiver perceptions on child's physical, emotional, social, and school functioning). Research about communication between caregivers and their children about weight and weight-related psychosocial impairments appears to be limited. Therefore, discrepancies in child and caregiver perceptions of QOL scores could be classified as a social concern, due to miscommunication regarding weight-related issues.

Child and Caregiver Discrepancies in QOL. Researchers indicate differences between child and caregiver perceptions regarding the overweight child's quality of life (Pinhas-Hamiel et al., 2006; Schwimmer et al., 2003; Williams et al., 2005). When child and caregiver perceptions of QOL are compared, caregivers report impaired QOL scores more often than their children (Pinhas-Hamiel et al., 2006; Zeller & Modi, 2006). Generally, caregivers report lower quality of life scores in all domains (physical, emotional, social, and school) when compared to childs'

scores (Pinhas-Hamiel et al., 2006). As children increase in weight category (e.g., from being overweight to obese), caregivers report lower quality of life scores for their children (Williams et al., 2005) with the most significant outcomes related to child's perceived physical health. Caregiver perceptions of children's psychosocial QOL did not appear to decrease as the child's weight category increased; however, children view their own psychosocial quality of life lower as their weight increased (Williams et al., 2005). Child and caregiver discrepancies in perceived child QOL functioning may indicate lack of or miscommunication between children and their caregivers. Children, specifically adolescents, often struggle developmentally with how to communicate or socialize with their caregivers. Hence, discrepancies between child and caregiver perception of QOL may initiate social conversations that otherwise would not have taken place. However, these conversations may be able to inform the child's treatment plan. The discrepancy in child and caregiver perceptions of QOL continues to prompt researchers to look at family-centered methods for assessment and treatment options for weight management.

Summary

The treatment of pediatric obesity has evolved from primarily a biomedical model utilizing only physicians, to the creation of treatment teams that offer diverse areas of expertise. This evolution is also evident in the new Expert Recommendations, which emphasize a family-centered approach for all stages of care (prevention through tertiary care) and the inclusion of multidisciplinary healthcare professionals (e.g., physicians, nutritionists, physical activity specialists, and behavioral health professionals). The new expert recommendations and current treatment of childhood obesity can be observed through the three-world view, in order to account for the strengths and challenges of providing care in the clinical world, forming policy and administrative support in the operational world, and billing and reimbursement through in the

financial world. The three-world view can aid healthcare systems and pediatric obesity programs in adapting to the changing needs of overweight children and their families as the focus of treatment expands to evidence-based interventions and the consideration of biopsychosocial indicators for overweight children.

Chapter 5: Method

Study Design and Sample

A longitudinal panel descriptive design is used for this study. This design allows for the investigation of multiple factors experienced by children who are overweight and their caregivers across up to three different integrated care visits (V1, V2, and V3) at a pediatric obesity treatment center. A sample was collected at the PHWRTC, which offers treatment for childhood obesity using a collaborative, biopsychosocial approach. The mission of the PHWRTC is to reduce childhood obesity in Eastern North Carolina, through collaboration with local health care providers and community agencies, and through the development, application, and dissemination of translational basic science and clinical research in both community and academic settings. Following the approval of the East Carolina University institutional review board, investigators began recruiting participants for the study.

Child participants are referred to the PHWRTC for clinical services from their primary care physician because of a concern about the child's weight and the risk of weight-related comorbidities. The PHWRTC serves families primarily from rural eastern North Carolina. Children and their caregiver(s) who are seen at the PHWRTC are diverse in their race, socioeconomic status (SES), and sex. Of the population seen at the PHWRTC, 70% receive Medicaid or Health Choice insurance and 63% are African American. Health Choice insurance is

for families who make too much money to qualify for Medicaid but too little money to afford health insurance premiums.

The research opportunity is presented to children ages 8-18 and their caregiver(s) at the child participant's initial visit to the PHWRTC. All participants are notified that clinical services are not contingent upon research involvement. At every visit subsequent to the initial, the research packet is re-administered with the same measures, excluding the family characteristic questionnaire. The PHWRTC is open two days a week with four time slots available on each given day for initial visits, and seven time slots for follow-up visits (which are often shorter in length). The primary investigator or a member of the research team makes a notation regarding which caregiver fills out the research packet at each visit.

Patients who are excluded from the research include children under the age of eight, who are wards of the state or live in a foster home environment, who are cognitively impaired (as identified by the electronic medical record or provider's evaluations), or do not speak English.

Location & Description of Clinical Services

The PHWRTC located in Greenville, NC, is committed to the prevention and treatment of childhood obesity by including the family, school systems, pediatricians, dieticians, and family therapists as a part of the child's overall care. Research takes place at the PHWRTC, Pediatric Specialty Unit (procedure described below). The PHWRTC is one of several clinics housed in the ECU Pediatric Specialty Unit. The PHWRTC operates out of one wing of a building consisting of a work space with multiple computers, desk room, and four designated patient rooms. Providers include three different physicians that rotate clinical time, one registered dietitian and licensed nutritionist, one doctoral level family therapist, and one master's level family therapy intern. At the initial visit to the PHWRTC, patients and their caregivers will

meet with several providers from different disciplines throughout the day. All providers (pediatrician, nutritionist, and family therapist) work from an integrated care model where care is shared among all providers with a high level of collaboration before, during, and after visits. Treatment plans are grounded in BPS constructs and are formulated with each team member's involvement as well as the families. According to the Expert Recommendations, the PHWRTC is a stage three or comprehensive multidisciplinary intervention.

Immediately following the patient's check-in and consent for treatment, the family is given an introduction/agenda for the day by the physician. First children have their blood work done in the PHWRTC lab. Blood work typically includes cholesterol, blood sugar, leptin, etc. In addition children over age seven, do an indirect caliometry which gives them their resting expenditure rate and approximates their ideal daily caloric intake. Height and weight are measured, BMI is calculated and plotted on age and gender appropriate charts and a blood pressure is taken.

The family therapist then greets the patient and family to assess for quality of life, and depression (via the PedsQL4.0 and PHQ9), and presents the research opportunity for those eligible patients (procedure described below). Following these measurements, patients receive a comprehensive integrated care BPS evaluation from general pediatrician, pediatric dietitian, and family therapist, all with a special interest and training in obesity. Patients will meet with the pediatrician for a medical history (i.e. number of hospitalizations, concerns related to weight of other family members) and physical exam. The family therapist intern is present during the medical history interview, providing psychosocial expertise when appropriate. The family therapist will also speak with the family after the medical encounter to address any relevant psychosocial issues. After the visit with the physician and family therapist, the patient will meet

with the nutritionist and develop goals related to nutrition. Children who already have noted joint complications are referred for physical therapy off-site.

Regular follow up appointments are scheduled, typically at least every three months and are shorter in duration. Height, weight, BMI and blood pressure are tracked by the nursing staff, and BMI percentile is plotted by the medical provider at each visit. Physical activity behaviors are tracked by the pediatrician at each visit and QOL and depression are tracked by the family therapist.

Measures

Researchers administer four instruments via the initial and follow-up research packets: a family characteristics questionnaire, Pediatric Quality of Life Inventory 4.0 (PedsQL4.0) with parallel child and caregiver modules, and a Patient Healthcare Questionnaire. These assessments were selected to provide a more comprehensive picture of the entire family.

Family Characteristics Questionnaire

A demographic questionnaire is administered at the initial visit to the child's caregiver. This questionnaire includes items such as race, age, sex, educational level, occupation, income, family structure, who lives in the household, and the age at which concerns arouse in regard to child's weight (see Appendix C). This questionnaire assists researchers in determining potential variables that could affect the family and child.

Pediatric Quality of Life Inventory 4.0

The PedsQL4.0 is used as an overall biopsychosocial healthcare assessment for PHWRTC patients and their caregivers. This tool addresses the biological system via the physical dimension, psychological system via the emotional dimension, and social system via the social and school dimensions. The PedsQL4.0 is cited in numerous publications on childhood

obesity attesting to its value. Schwimmer, Burwinkle, & Varni (2003) found that the total scale score for both the child and caregiver reports has demonstrated at least a Cronbach α reliability coefficient of .90, thus can be utilized for individual patient analysis and as a health related quality of life outcome measure for clinical trials. This measure is also recognized for the age appropriateness for children (ages 5 to 18) and parallel caregiver module that is also available. There are different age appropriate module levels for children to complete: young child (5-7 years old), child (8-12 years old), and teen (13-18 years old).

All three PedsQL4.0 modules consist of 23 items. The 23 items are broken down into four dimensions: physical functioning, emotional functioning, social functioning, and school functioning. Items are ranked on a reverse-likert scale ranging from (0) never a problem, (1) almost never a problem, (2) sometimes a problem, (3) often a problem, to (4) almost always a problem. In another population, the Cronbach reliability of the PedsQL4.0 is .88 for the child modules and .90 for the caregiver modules (Schwimmer et al., 2003).

Patient Healthcare Questionnaire

The Patient Healthcare Questionnaire (PHQ-9) (Pfizer, 2000) assesses depressive symptoms experienced throughout the two-week time frame prior to completing the measure. The PHQ-9 consists of nine questions, with responses ranging from: not at all (0), several days (1), more than half the days (2), and nearly every day (3). The result from the PHQ-9 is a depression severity score, ranging from no depression (0-4), mild depression (5-9), moderate depression (10-14), moderately severe depression (15-19), and severe depression (20-27). This measure is used to assess for depression and suicidal ideation in caregivers and overweight children (≥13) seen at the PHWRTC. The test-retest reliability scores for this measure range from .68 to .95. In addition, the PHQ-9 is administered to caregivers to explore their depressive

symptoms and psychosocial status. Fatigue is assessed via two questions on the PHQ9: 1) “feeling tired or having little energy” and 2) “trouble falling or staying asleep, or sleeping too much”.

The PHQ-9 is appropriate for individuals aged 13 and older to complete. Therefore, children younger than 13 years have depression assessed via the social and emotional subscales, of the PedsQL4.0.

Health Status Variables

In addition to the previously mentioned assessments we request biological and physiological indicators from patients to evaluate health status variables. BMI and BP are common health indicators used for children who are overweight or obese. For children with a BMI above the 99th percentile a BMI z-score (standard deviation) is more sensitive for monitoring changes in BMI. A BMI z-score is a way to express the distance between an individual child's weight and the average weight of a comparable population (i.e., overweight or obese children). In addition to these indicators, we included physical activity levels and nutrition behaviors as additional BPS health status variables. It is recommended that all youth get daily at least 60 minutes, of physical activity or active play (Barlow, 2007). The PHWRTC determines physical activity level by four criteria: 1) the type of activity (walking, running, biking, active games, organized sports, organized exercise, or other), 2) the duration of exercise (indicated by how many minutes on average for the type of activity; ranging from 15, 30, 45, 60), 3) the intensity of exercise (classified as low, medium, or high), and 4) the frequency of exercise (indicated by how many days per week ranging from 1-7). Nutrition behaviors will be determined by daily intake of fruits and vegetables (based on the combined number in a typical day) and consumption of sugar sweetened beverages (indicated by ounces per day).

Readiness to Change

Finally, at each visit to the PHWRTC, the attending physician indicates how likely he or she believes the child and caregiver were to make changes. Responses for "readiness to change" are recorded for the child and caregiver separately on a likert scale: Likely to make changes (3), may make changes (2), unlikely to change (1), stated will not change (0), and unable to evaluate.

Procedure

At the patients' initial visit, the research opportunity is presented to the child and his/her caregiver. The researchers inform all participants that care is not contingent upon completion of research and that participation is voluntary. Less than five caregivers have declined the opportunity to participate in the research, primarily due to their personal time constraints. Prior to the modules being administered, participants must sign an informed consent, along with a signed assent form from the child.

The child research packet contains the age appropriate PedsQL4.0 and PHQ-9 assessments for children ages 8-18. For children under 13 years of age, depression is assessed via the emotional and social domains of the PedsQL. If questions arise while the child or caregiver(s) is taking the survey, a member of the research team is available to provide clarity or answer questions. A member of the research team is available to assist children who have trouble reading, by reading aloud the questions and circling the corresponding answer that the child selects.

Upon completion of the research packets, the PI or the family therapy intern scores the measures immediately for clinical relevance. Results are discussed with the patient at the end of the visit with the physician present. It is important to note that these measures are used for

research purposes as well as clinically, to promote discussions about biopsychosocial indicators at post-visits with children and caregivers.

At subsequent visits, children and their caregivers are asked again to fill out the research packets. If a different caregiver attends the follow-up session that did not fill out the initial research at the first visit, it is noted and recorded in the database.

After data collection is complete, child and caregiver scores are entered into a statistical database (SPSS) by the PI. The database is managed by the PI, and updated weekly with new participants' research. The research packets are stored under double lock and key. Child participants' medical charts are retrieved by the PI in order to extract Body Mass Index (BMI), medical comorbidities, and nutrition and physical activity related behaviors.

Statistical Analysis

All analyses will be carried out with SPSS version 15.0 (SPSS Inc., 2004).

2. What are the baseline characteristics of the children and their caregivers in terms of age, ethnicity, sex, caregiver relationship to the children, QOL total and scale scores, QOL discrepancy between child and caregiver, depression levels of child (adolescent) and caregiver, health status (including BMI (z-score), BP, nutrition behaviors, and physical activity), and readiness for change?

The analysis strategy for this question would include the following:

- Check all variables for missing data and data entry errors
- Check all quantitative variables for skewness and outliers.
- Run frequencies on all categorical variables and means/SD's on all quantitative variables.
- Compute coefficient alpha for all scale data (QOL and PHQ9).
- Compute child-caregiver discrepancy scores on QOL total score and scale scores.

- Develop categories for nutrition behaviors, physical activity, readiness for change, PHQ9 scores, child-caregiver QOL discrepancy scores, and time between visits.

4. At baseline, what are the relationships between (1) QOL, BMI (z-score), physical activity; (2) QOL child and caregiver discrepancy scores and child QOL; (3) QOL and PHQ9 scores; (4) QOL and readiness to change; (5) nutrition behaviors and BMI (z-score); and (6) nutritional status and QOL, and are these relationships related to the child's age, sex, or ethnicity?

The analysis strategy for this question would include the following:

- Compute Pearson correlations to explore relationships between quantitative variables for total group, and within sex/ethnicity subgroups.
- Use one-way anova to compare mean QOL scores between readiness to change categories and between nutrition behaviors categories separately for total group and for sex/ethnic subgroups.
- Use one-way anova to compare mean BMI between nutrition behaviors categories for total group and for sex/ethnic subgroups.

5. Are there changes in QOL, BMI (z-score), PHQ9, nutrition behaviors, and physical activity from V1 (initial visit) to V2 (first follow-up visit) to V3 (second follow-up visit) for the total group?

The analysis strategy for this question would include the following:

- For complete data at V1 and V2, and for complete data at V1, V2, and V3, one-way repeated measures anova will be used to compare QOL, BMI (z-score), PHQ9, exercise frequency, and nutrition behaviors.

5. Are the V1 – V2, and V1 – V2 – V3 changes in QOL, BMI (z-score), PHQ9, exercise frequency, and nutrition behaviors related to (1) child's age at V1; (2) child's ethnicity; (3) time between visits; (3) V1 BMI category; (4) readiness for change at V1 or V2; (5) V1 family structure (one or two caregivers); (6) level of discrepancy between child and caregiver QOL at V1 or V2; or (7) sex of the child?

The analysis strategy for this question would include the following:

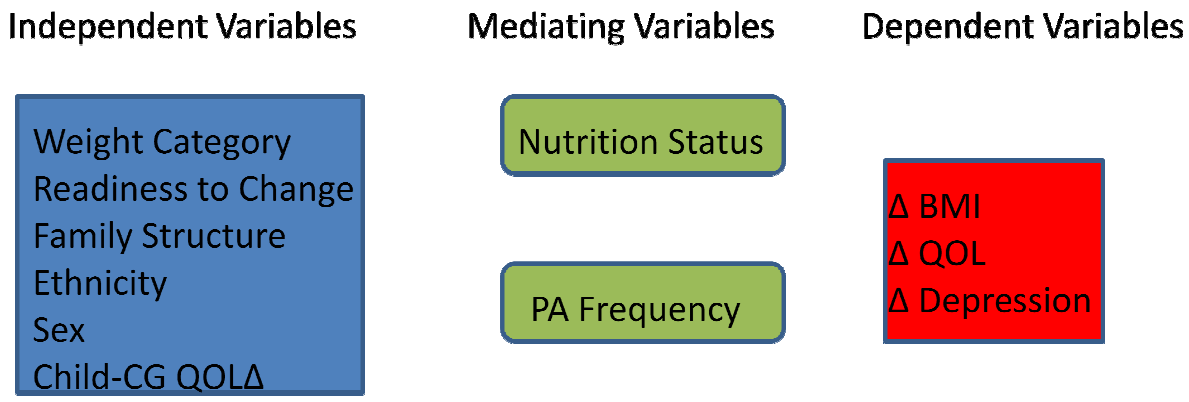
- A mixed between-within subjects anova for complete data on V1 and V2, and for complete data on V1, V2, and V3 will be used to compare QOL, BMI, PHQ, exercise frequency, and nutrition behaviors.

5. Are there V1 variables related to V2 attrition, and V1 and V2 variables related to V3 attrition?

The analysis strategy for this question would include the following:

- A multivariate logistic regression will be used to predict the probability of not keeping a V2 appointment (dependent variable), and the probability of not keeping a V3 appointment (dependent variable). Independent variables will be screened for association with the dependent variables at a p-value of <0.25, and those variables passing the screen will be entered as one block into a logistic regression model. Variables that have statistically significant odds ratios will be evaluated as potential predictors of attrition.

Logic Model for V2 and V3 visits



Reporting of the Results

After synthesizing the literature related to pediatric obesity, the three-world view, integrated care, and outcomes addressing the biopsychosocial dimensions for children and caregivers the dissertation will be broken into two articles. The first article is under review in the *Journal of Integrated Care*. Article two will be submitted to one pediatric journal, which will either be *Contemporary Pediatrics* or *Ambulatory Pediatrics*. The journals selected have a diverse readership from integrated care and pediatric audiences, all of which have multidisciplinary readership.

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Table 1: Important Terms

Term	Definition	Example
Behavioral Health	Serves as an overarching term encompassing "mental health", "substance abuse", and "behavioral medicine." (Blount et al., 2007)	An individual working with an obese child who is trained in behavioral health may be a family therapist, psychologist, psychiatrist, social worker, or case manager.
Behavioral Medicine	Services designed to intervene on physical health using behavioral means. (Blount et al., 2007)	Behavioral medicine services may include but are not limited to health behavior change programs, education for coping with illness, programs to improve adherence to medical regiments, and services that access the relaxation response (e.g., relaxation training, biofeedback, mindfulness).
Collaborative Care	A team with at least one medical provider and one behavioral health provider. Collaboration is an understanding that improvements in patient care are achieved more efficiently by working together and focusing on systems than they would be by working independently and focusing on individuals. (Blount et al., 2007; Kilo, 1999).	A physician, nutritionist, and behavioral health professional all view a patient and his or her family as the focus of treatment. There is shared communication around treatment goals and progress.
Co-located Services	Places multiple services in the same physical space in hopes that close proximity will enhance the outcome of services for a population. Co-location goes beyond sharing the same physical space to include the same office staff and waiting facilities (Blount et al., 2007; Ginsburg, 2008)	For example, a pediatrician and nutritionist may share the same secretarial support, nursing/laboratory services, as well as examination rooms. *It is possible for services to be co-located and not coordinated, and may be integrated and not co-located (Blount, 2003).
Coordinated Services	Coordinated care can range from informal to formal depending on the level of patient care and communication among providers. Healthcare providers that jointly review cases, treatment plans, or needed referrals are coordinating care. (Ginsburg, 2008)	A physician that communicates with a nutritionist regarding a patient's treatment plan is coordinating care.
Family-centered Care	Based on the understanding that the family is the child's primary source of strength and support and that the child and family's perspective and information are important in clinical decision making. It is an approach to prevention, assessment, and treatment that considers not only the child as the identified patient but the family that the child is in consistent contact with. (Pediatrics, 2007)	A family-centered weight loss program includes praising the child's healthy behavior choices, not disciplining with food (e.g., no rewards), providing structured feeding times, deciding what healthy options are offered, removing temptations from the child's environment, parental modeling of health behaviors, and providing all of the above consistently in the home (Barlow & Dietz, 1998).
Integrated Care	Integrated care is collaborative care that addresses the biopsychosocial symptoms of patients. Care is highly coordinated between medical and mental health providers, which can be seen through shared treatment plans (Patterson et al., 2002). What separates integrated care from collaborative care is the appearance of the "unified provider." Integrated care involves at least one medical and behavioral health	Often in an integrated care setting a medical and behavioral health provider will provide side-by-side services for a patient (Patterson et al., 2002). Integrated care may involve more than a medical and behavioral health provider; as is the case with childhood obesity where often a physical therapist, case manager, and nutritionist or dietician is included as well. In an integrated care consult a physician and behavioral health

	provider incorporated into a patient's treatment plan. (Blount, 2003)	professionals may see a patient together in the same physical space at the same time.
Multidisciplinary Care	Includes the expertise of several different disciplines (e.g., medical, nutrition, endocrine, family therapy, exercise physiology).	For example an overweight child may see a nutritionist, pediatrician, and exercise physiologist, possibly at different appointments or settings.

Table 2: Summary of the Expert Recommendations and the Three-world View at the Recommended Stages of Obesity Treatment.

	Clinical World	Operational World	Financial World
Stage 1: Prevention Plus	• Family Centered • Referrals for outside care if necessary (e.g. nutrition)	• Primary provider (e.g. physician) administrative support in scheduling for one primary provider's patients • Information for referrals offsite	• Reimbursable medical procedures as done by a physician
Stage 2: Structured Weight Management	• Family Centered • Multidisciplinary with an added healthcare professional with childhood obesity expertise (typically a nutritionist at this stage) • Coordinated Care for offsite referrals *no detail about collaboration with the added healthcare professional	• Provider (e.g. physician and nutritionist) administrative support with scheduling and for additional providers • Information sharing and releases *no detail about how to scheduling or administrative support for the added healthcare professional	• Reimbursable medical procedures as done by a physician *no detail about how to reimburse for the added healthcare professional
Stage 3: Multidisciplinary Intervention	• Family Centered • Multidisciplinary with the addition of behavioral treatment • Coordinated Care of services either on or offsite *No detail on communication with or collaboration with the added healthcare professionals (e.g. shared treatment planning and goals)	• Multiple provider administrative support • Information sharing and releases • Shared nursing staff and medical facilities • Shared treatment plans *No detail about how administrative support facilitates multiple providers (e.g. scheduling, nursing services, etc)	• Reimbursable medical procedures as done by the physician *No detail about how to reimburse for multiple providers in the same physical setting on the same day.
Stage 4: Tertiary Care Intervention	• Family Centered • Multidisciplinary with Behavioral Treatment • Coordinated Care	• Providers administrative support • Information sharing and releases • Shared nursing staff and medical facilities • Treatment team meetings *No detail about how administrative support	• Reimbursement for higher level services • Bundled services

	*No detail about collaborative or integrated care treatment team facilitation (team meetings, patient flow, and shared treatment planning).	facilities multiple providers (e.g. scheduling, nursing services, etc).	*No detail about how to reimburse for multiple providers in the same physical setting on the same day.

Appendix C: Inventories

ID#
_____

Date:_____
_

PedsQL™

Pediatric Quality of Life Inventory

Version 4.0

CHILD REPORT (ages **8-12**)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month**, how much of a **problem** has this been for you …*

ABOUT MY HEALTH AND ACTIVITIES *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. It is hard for me to walk more than one block	0	1	2	3	4
2. It is hard for me to run	0	1	2	3	4
3. It is hard for me to do sports activity or exercise	0	1	2	3	4
4. It is hard for me to lift something heavy	0	1	2	3	4
5. It is hard for me to take a bath or shower by myself	0	1	2	3	4
6. It is hard for me to do chores around the house	0	1	2	3	4
7. I hurt or ache	0	1	2	3	4
8. I have low energy	0	1	2	3	4

ABOUT MY FEELINGS *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. I feel afraid or scared	0	1	2	3	4
2. I feel sad or blue	0	1	2	3	4
3. I feel angry	0	1	2	3	4
4. I have trouble sleeping	0	1	2	3	4
5. I worry about what will happen to me	0	1	2	3	4

HOW I GET ALONG WITH OTHERS *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. I have trouble getting along with other kids	0	1	2	3	4
2. Other kids do not want to be my friend	0	1	2	3	4
3. Other kids tease me	0	1	2	3	4
4. I cannot do things that other kids my age can do	0	1	2	3	4
5. It is hard to keep up when I play with other kids	0	1	2	3	4

ABOUT SCHOOL *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. It is hard to pay attention in class	0	1	2	3	4
2. I forget things	0	1	2	3	4
3. I have trouble keeping up with my schoolwork	0	1	2	3	4
4. I miss school because of not feeling well	0	1	2	3	4
5. I miss school to go to the doctor or hospital	0	1	2	3	4

ID#
_____

Date:_____
_

PedsQL™

Pediatric Quality of Life Inventory

Version 4.0

TEEN REPORT (ages **13-18**)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month**, how much of a **problem** has this been for you …*

ABOUT MY HEALTH AND ACTIVITIES *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. It is hard for me to walk more than one block	0	1	2	3	4
2. It is hard for me to run	0	1	2	3	4
3. It is hard for me to do sports activity or exercise	0	1	2	3	4
4. It is hard for me to lift something heavy	0	1	2	3	4
5. It is hard for me to take a bath or shower by myself	0	1	2	3	4
6. It is hard for me to do chores around the house	0	1	2	3	4
7. I hurt or ache	0	1	2	3	4
8. I have low energy	0	1	2	3	4

ABOUT MY FEELINGS *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. I feel afraid or scared	0	1	2	3	4
2. I feel sad or blue	0	1	2	3	4
3. I feel angry	0	1	2	3	4
4. I have trouble sleeping	0	1	2	3	4
5. I worry about what will happen to me	0	1	2	3	4

HOW I GET ALONG WITH OTHERS *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. I have trouble getting along with other teens	0	1	2	3	4
2. Other teens do not want to be my friend	0	1	2	3	4
3. Other teens tease me	0	1	2	3	4
4. I cannot do things that other teens my age can do	0	1	2	3	4
5. It is hard to keep up with my peers	0	1	2	3	4

ABOUT SCHOOL *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. It is hard to pay attention in class	0	1	2	3	4
2. I forget things	0	1	2	3	4
3. I have trouble keeping up with my schoolwork	0	1	2	3	4
4. I miss school because of not feeling well	0	1	2	3	4
5. I miss school to go to the doctor or hospital	0	1	2	3	4

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME: _____ **DATE:** _____

Over the *last 2 weeks*, how often have you been bothered by any of the following problems? *(use "✓" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3
add columns:		+	+	
(Healthcare professional: For interpretation of TOTAL, please refer to accompanying scoring card.) **TOTAL:**				

10. If you checked off *any* problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?	**Not difficult at all** _____ **Somewhat difficult** _____ **Very difficult** _____ **Extremely difficult** _____

ZT274388

BACKGROUND SURVEY

Instructions: If you are a caregiver of a child attending the Pediatric Healthy Weight Clinic, and are 18 years of age or older, you will be completing this form about yourself and the child. Questions will either ask for the "**patients**" information or "**your**" information.

1. What is the **patient's** age? (Please write in the patient's current age here.) _____

2. What is the **patient's** sex? (Check the appropriate line.)
_____Male
_____Female

3. What is the **patient's** race? (Check the appropriate race.)
_____Caucasian/White
_____African American/Black
_____Mexican/Mexican American/Chicano
_____Puerto Rican
_____Cuban
_____American Indian/Alaskan Native
_____Asian Indian
_____Chinese
_____Other (please write here.)_____
_____Filipino
_____Japanese
_____Korean
_____Vietnamese
_____Native Hawaiian
_____Guamanian
_____Chamorro
_____Other Pacific Islander

4. How old was the **patient** when you became concerned about his/her weight? _____
or check here if you have never been concerned _____

5. What is the **patient's** current grade? _____
If not in school what is the patients highest grade completed? _____

6. What language is spoken in household where the **patient** lives? (Check the appropriate line.)
_____English
_____Spanish
_____Other (Please write here.) _____

7. Has the **patient** attempted methods of weight loss/control before? (Check the appropriate line.)
_____Yes (If yes, what?) _____
_____No

8. Is the **patient** currently trying to lose weight? (Check the appropriate line.)
_____Yes
_____No

9. What is the **patient's** current health insurance plan? (Check the appropriate line.)
_____Traditional health insurance (Fee for service where you choose your doctor and most fees are covered)
_____Health maintenance organization (HMO)
_____US government plan (CHAMPUS)
_____Medicaid
_____NC Health Choice
_____None
_____Other (Please write here.) _____

10. What is **your** age? (Please write in your age your current age here.) _____

11. What is **your** sex? (Check the appropriate line.)
_____Male
_____Female

12. What is **your** relation to the patient? (Check the appropriate line.)
_____Mother (biological)
_____Father (biological)
_____Sister (biological)
_____Brother (biological)
_____Step-mother
_____Step-father
_____Other (Please write here.) _____
_____Grandmother (biological)
_____Maternal
_____Paternal
_____Grandfather (biological)
_____Maternal
_____Paternal

13. What is **your** race? (Check the appropriate race.)
_____Caucasian/White
_____African American/Black
_____Mexican/Mexican American/Chicano
_____Puerto Rican
_____Cuban
_____American Indian/Alaskan Native
_____Asian Indian
_____Chinese
_____Other (Please write here.) _____
_____Filipino
_____Japanese
_____Korean
_____Vietnamese
_____Native Hawaiian
_____Guamanian
_____Chamorro
_____Other Pacific Islander

14. What is **your** highest level of education? (Check the appropriate level.)
_____Grammar School (1^{st}-8^{th} grade)
_____Some High School
_____High School
_____Some College (no degree)
_____Vocational/Technical/Associates Degree (2 years)
_____Other (Please write here.) _____
_____College Graduate (4 years)
_____Master's Degree
_____Doctoral Degree
_____Graduate of Professional Degree (e.g. M.A., M.S., Ph.D., M.D.)

15. Are **you** currently employed? (Check the appropriate line.)
_____Yes (go to #16)
_____No (go to #17)

16. If you answered yes to question 15, what is **your** occupation?
(Please write here.) _____

17. If you answered no to question 15, do any of the following apply to **you**? (Check all that apply.)
_____Retired
_____Disabled
_____Full-time student
_____Looking for work

Who lives in the same household as the patient and what is his/her relationship to the patient? (List below.)

Name:	**Age(s):**	**Sex:** (male/ female)	**Relationship to Patient:** (e.g. mother, father, etc)	**Race/Ethnicity:** (Please use the categories used in question #3.)

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME: _____ **DATE:** _____

Over the *last 2 weeks*, how often have you been bothered by any of the following problems? *(use "✓" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3
	add columns:		+	+
(Healthcare professional: For interpretation of TOTAL, please refer to accompanying scoring card.)	**TOTAL:**			

10. If you checked off *any* problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?	**Not difficult at all** _____ **Somewhat difficult** _____ **Very difficult** _____ **Extremely difficult** _____

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PARENT REPORT for **CHILDREN** (ages **8-12**)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month,** how much of a **problem** has your child had with…*

PHYSICAL FUNCTIONING *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Walking more than one block	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activity or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him or herself	0	1	2	3	4
6. Doing chores around the house	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Low energy level	0	1	2	3	4

EMOTIONAL FUNCTIONING *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or blue	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Getting along with other children	0	1	2	3	4
2. Other kids not wanting to be his or her friend	0	1	2	3	4
3. Getting teased by other children	0	1	2	3	4
4. Not able to do things that other children his or her age can do	0	1	2	3	4
5. Keeping up when playing with other children	0	1	2	3	4

SCHOOL FUNCTIONING *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with schoolwork	0	1	2	3	4
4. Missing school because of not feeling well	0	1	2	3	4
5. Missing school to go to the doctor or hospital	0	1	2	3	4

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PARENT REPORT for **TEENS** (ages **13-18**)

DIRECTIONS

On the following page is a list of things that might be a problem for **your teen**. Please tell us **how much of a problem** each one has been for **your teen** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month,** how much of a **problem** has your teen had with …*

PHYSICAL FUNCTIONING *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Walking more than one block	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activity or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him or herself	0	1	2	3	4
6. Doing chores around the house	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Low energy level	0	1	2	3	4

EMOTIONAL FUNCTIONING *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or blue	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Getting along with other teens	0	1	2	3	4
2. Other teens not wanting to be his or her friend	0	1	2	3	4
3. Getting teased by other teens	0	1	2	3	4
4. Not able to do things that other teens his or her age can do	0	1	2	3	4
5. Keeping up with other teens	0	1	2	3	4

SCHOOL FUNCTIONING *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with schoolwork	0	1	2	3	4
4. Missing school because of not feeling well	0	1	2	3	4
5. Missing school to go to the doctor or hospital	0	1	2	3	4