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Obesity in Adolescence: An Epidemic in the Face of Modern Medicine

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Chapter 1 - Introduction

The identification and treatment of obesity in children and adolescents currently is a major problem that needs to be overcome in the Primary Care setting. The battle with obesity is considered a national priority, according to the Healthy People 2010 objectives (Drohan, 2002, Kealy, 2003). Recently, it was estimated that the cost to society per year was 99 billion dollars to cover medical expenses incurred due to obesity (Drohan, 2002; Jerum and Melnyk, 2001). In addition, the direct costs of Type 2 diabetes, and the indirect costs associated with other comorbidities, such as hypertension, hyperlipidemia, and cardiovascular disease, were estimated to be 63 billion dollars per year in the United States (Drohan, 2002). As a result of the estimated healthcare costs related to childhood obesity leading to comorbidities in adulthood, the surgeon general has stated that preventable mortality and morbidity might surpass those linked with cigarette smoking (American Academy of Pediatrics, Committee on Nutrition, 2003). However, it continues to be an ongoing struggle as Primary Care providers are burdened with time constraints and decreasing insurance coverage for their patients (American Academy of Pediatrics, Committee on Nutrition, 2003; Jerum and Melnyk, 2001). Currently, Medicare and Medicaid will not reimburse physicians for obesity unless the patient has related comorbidities. Obesity itself is not considered a disease (Moore, 2003). The potential for mid-level providers to identify children and adolescents at risk and to pursue treatment options is greatly underutilized (Drohan, 2002; Jerum and Melnyk, 2001). Background

Several studies, utilizing the data from the National Health and Nutrition

Examination Survey (NHANES), show a proportional increase in obesity in adolescents

to that of adults (Drohan, 2002, Kealy, 2003). The correlation between obesity and other comorbidities, such as type 2 diabetes, hypertension, hyperlipidemia, orthopedic problems, obstructive sleep apnea, polycystic ovary syndrome, and psychosocial problems, is well documented (Barlow and Dietz, 1998; Drohan, 2002; Hodges, 2003, Pinhas-Hamiel and Zeitler, 2001).

It is currently estimated that approximately 20-30% of children and adolescents in the United States are obese (Bar-Or, 2000; Fowler-Brown and Kahwati, 2004; Jerum and Melnyk, 2001). Childhood and adolescent obesity greatly increases the risk of obesity in adulthood, but these risks, and the development of comorbidities, can be prevented by the incorporation of total lifestyle modifications (Bar-Or, 2000; Fowler-Brown and Kahwati, 2004; Frenn, Malin, and Bansal, 2003; Hodges, 2003; Yackel, 2003, Kealy, 2003).

The recommendations for weight loss and maintenance of weight loss go beyond just diet and exercise. The standard of care practice needs to incorporate diet, exercise and behavior modifications, along with assessing the readiness of the child to begin a treatment program and educating the child and parent of the risks associated with obesity (Ariza, Greenberg, and Unger, 2004; Barlow and Dietz, 1998; Bar-Or, 2000; Fowler-Brown and Kahwati, 2004; Nestle and Jacobson, 2000). It has been suggested that the support of family, friends, and school based programs and clinicians are essential in order to sustain healthy lifelong lasting changes (Barlow and Dietz, 1998).

Problem Statement

Despite our ability to identify, diagnose, and treat obesity in children and adolescents, its prevalence continues to increase at an alarming rate. The reasons for this remain unclear.

Purpose

The purpose of this study was two-fold, first to assess the level of identification of obese children and adolescents in the Primary Care setting, and second to evaluate the implementation of a treatment plan in accordance with current standard of care practices (Bar-or, 2000; Nestle and Jacobson, 2000). From reviewing the charts the following questions were answered, (1) was there sufficient information to appropriately evaluate for obesity (growth chart, and/or weigh and height); (2) if there was adequate information to make the diagnosis of obesity, was it documented in the problem list; (3) when there was a diagnosis of obesity in the problem list was there an appropriate treatment plan implemented. It would be presumptuous to say that clinicians evaluate and treat all children and adolescents with obesity, consistent with current standard of care practices. The relevance of this study is associated with the increasing prevalence of obesity in young people, as well as the potential related comorbidities.

Although this is limited to one clinical site, a step, however small it may be, in the right direction to prevention as well as identifying those at risk earlier may begin to reverse the current trend. The results of this study may be able to assist the Medical College of Ohio (MCO) Family Practice clinicians to be more aware of their existing efforts related to the recognition and treatment of obesity in children and adolescents.

Chapter 2 - Literature Review

When referring to overweight and obesity, there is a distinct difference. The term overweight refers to excess weight for height, which includes muscle, bone, fat and/or water weight (Kealy, 2003). The term obesity refers to excess body fat, which is determined by the Body Mass Index (BMI) (Barlow and Dietz, 1998; Dietz and Bellizzi, 1999; Hodges, 2003; Kealy, 2003). For adults BMI is calculated by taking the weight in kilograms divided by the height (m²) and is currently the accepted method used to determine whether children and adolescents are overweight or obese. Adults having a BMI less than 24.9 kg/m² is considered normal or healthy, a BMI between 25-29.9 kg/m² is considered overweight, a BMI >30 kg/m² is considered obese, and having a BMI >40 kg/m² is morbidly obese (Kealy, 2003, Mitgutsch and Boardley, 2003). For children, the designated guidelines to distinguish overweight from obesity are based on BMI percentile for age and sex. A copy of the CDC published body mass index for age percentile of boys and girls aged 2-20 years can be found in Appendix A. A BMI >85th - <95th percentile, indicates an individual at risk for overweight, and a BMI > 95th percentile is considered overweight/obese (American Academy of Pediatrics, Committee on Nutrition, 2003; Dennison and Boyer, 2004, Dietz and Bellizzi, 1999; Hodges, 2003; Jerum and Melnyk, 2001; Mitgutsch and Boardley, 2003, Whitaker et al., 1997). Other methods of measurement, such as skinfold thickness were considered to correlate well with percent body fat, but the difficulty was in the consistency of the person taking the measurement and the subject's degree of obesity (Dietz and Bellizzi, 1999; Hodges, 2003).

Data that was gathered by the Center for Disease Control's (CDC) Third National Health and Nutrition Examination Survey (NHANES III) recognized rates of obesity in

children and adolescents to be an epidemic (American Academy of Pediatrics, Committee on Nutrition, 2003; Davis, Davis, Northington, Moll, and Kolar, 2002). Estimates of children and adolescents in the United States who are considered overweight/obese, is one in five (Barlow and Dietz, 1998; Davis et al., 2002; Drohan, 2002; Yackel, 2003).

Many risk factors that predispose children and adolescents to being overweight/obese have been identified. Several studies have looked at the impact of ethnicity and socioeconomic status (SES) regarding overweight/obesity in children and adolescents. A study performed by the CDC and the United Nations Children's Fund (UNICEF) examined the prevalence of overweight preschool aged children in low-income families, from 1983 to 1995. The results reported an increase from 18.6% to 21.6% in 1983 at the 85th percentile and an increase from 8.5% to 10.2% in 1995 at the 95th percentile (Drohan, 2002; Hodges, 2003; Mei et al. 1998).

Another study showed that children and adolescents of lower socioeconomic status are more likely to consume foods with a higher caloric content and more saturated fat than they are to choose more nutritious foods, such as fruits and vegetables (American Academy of Pediatrics, Committee on Nutrition, 2003).

Troiano and Flegal, (1998) reported, based on data collected from NHANES III, that there was an increase in the prevalence of obesity in African American and Hispanic children when compared to Caucasian children. However, they concluded that a low SES was not related to increased prevalence of obesity in African American and Hispanic children but there was an inverse relationship between increased prevalence and a high SES for Caucasian children.

A study by Robinson, Chang, Haydel, and Killen, (2001) took 969 children with a mean age of 8.5 years in northern California and looked at the assessments of third grade girls and boys concerning issues of overweight, desired shape, and body dissatisfaction. They specifically were interested in the influence of ethnicity and socioeconomic status. Their sample was 44% Caucasian, 21% Latino, 19% non-Filipino Asian American, 8% Filipino and 5% African American. In general, Latino and African American girls voiced more concerns regarding overweight issues than did Asian Americans and Filipinos; and Latino girls reported more concerns than Caucasian girls. There were a higher percentage of girls who reported wanting to lose weight as well as dieting to lose weight, compared to that of boys. It also showed that higher SES among African American girls was related to increased concerns regarding overweight issues. However, higher SES among Caucasian girls was linked to decreased concerns regarding overweight issues. They concluded that there was no significant difference in the prevalence of concerns regarding overweight issues across ethnicity and SES.

Another study by Gordon-Larsen, Adair, and Popkin, (2003) looked at the relationship between ethnicity, SES, parental education, and age and gender differences among Caucasian, African American, Hispanic, and Asian adolescents. There was no significant difference among prevalence of overweight adolescents when the income and parents level of education were considered. The disparity of ethnicity and SES regarding the prevalence of overweight adolescents was greater in girls than in boys. It also showed that there was an increase in the prevalence of overweight adolescents among African Americans and a decrease among Caucasian adolescents when looking at the highest SES. When they looked at the prevalence among Caucasian, Hispanic, and Asian

females there was not a significant difference at the highest SES. They concluded that there was a difference in the prevalence among ethnicities but it was not necessarily related to SES or the level of parental education.

Crawford et al., (2001) noted that Caucasian children were at a lower risk of becoming obese than African-American or Hispanic children but found that a higher SES does not necessarily lead to a decreased prevalence of obesity. They suggested that environmental changes related to increased caloric intake and decreased energy expenditure had more of an impact.

Other risk factors that are considered non-modifiable include genetics, early menarche, high birth weight, and the period of adipose rebound. As documented by Whitaker et al., (1998) adiposity rebound refers to the point of maximal leanness or minimal BMI. Adipose rebound occurs normally at 5-6 years of age, where there is a decrease in body fat and then adipose rebound begins to increase through adolescence into adulthood. They found that a child who reached adipose rebound at a younger age was at an increased risk of developing adult obesity. Modifiable risk factors consist of environment, maternal diabetes, maternal obesity, poor diet, increase in sedentary activities, decrease in physical education programs.

The tendency for overweight/obese children and adolescents to become obese adults is not disputed. It was reported that the percent of overweight children 6 years of age or older have a 50% chance of becoming an overweight adult (Bar-Or, 2000; Whitaker, Wright, Pepe, Seidel, and Dietz, 1997); overweight adolescents becoming overweight or obese adults is 70% and the percent increases to 80% if at least one parent is overweight or obese (Bar-Or, 2000; Fowler-Brown and Kahwati, 2004; Frenn, Malin,

and Bansal, 2003; U.S. Office of the Surgeon General, 2001). Whitaker et al. (1997) found that obese children less than 3 years of age who didn't have obese parents were at low risk for developing obesity in adulthood. They also report that obese adolescents have a greater risk of becoming an obese adult regardless of whether of not the parents are obese.

The association between noninsulin-dependent diabetes mellitus (NIDDM) and obesity in children and adolescents is reaching epidemic proportions (Zielke, 2002). According to Moore, (2003) the number of children diagnosed with Type 2 diabetes went from 4% in 1990 to 20% in 2000 and of these children 85% were considered to be overweight or obese. Another study indicated a significant association between NIDDM and obesity, finding that 92% of the adolescents participating had a BMI greater than the 90th percentile (Scott, Smith, Cradock and Pihoker, 1997). The long-term negative health consequences associated with Type 2 diabetes are, an increased rate in the development of cardiovascular disease, neuropathy, retinopathy, nephropathy, and peripheral neuropathy (Jerum and Melnyk, 2001; Pinhas-Hamiel and Zeitler, 2001). Type 2 diabetes is just one of the potential comorbidities that is associated with obesity.

Other comorbidities found in children and adolescents related to obesity include orthopedic complications such as slipped capital femoral epiphysis, and Blount's disease (genu varum). Cardiovascular complications include hypercholesterolemia and hypertension. In addition to NIDDM, endocrinologic disorders include polycystic ovarian syndrome and menstrual irregularities. Although, enlarged tonsils may be the cause of breathing difficulties and snoring, potentially fatal disorders such as sleep apnea and obesity hypoventilation syndrome may occur.

However, in our society, the psychosocial impact of obesity may outweigh all the other comorbidities. Adolescents suffer from low self-esteem, social rejection, and depression (American Academy of Pediatrics, Committee on Nutrition, 2003; Barlow and Dietz, 1998; Hodges, 2003; Mei et al., 1998). Moore, (2003) studied the NHANES data and concluded that up to 30% of obese girls and 20% of obese boys ages 15 to 19 were depressed. The risk of potentially developing an eating disorder has also been reported. The prevalence of overweight adolescent females binge eating is estimated to be 30% (Barlow and Dietz, 1998; Fowler-Brown and Kahwati, 2004).

There are several studies that have examined the appropriate treatment for the current epidemic of overweight/obesity in children and adolescents. Being able to identify those at risk for overweight is vital to prevention. It has been suggested that each patient needs to have his or her BMI assessed at every opportunity, including well-child visits, acute/sick visits, for school, work, or sports physicals, and even for summer camps (Dennison and Boyer, 2004; Fowler-Brown and Kahwati, 2004). This may prove difficult to monitor at "every" visit but it is strongly encouraged to at least monitor the BMI yearly (Ariza, et al., 2004; Mitgutsch and Boardley, 2003; Schwimmer, 2004). The Centers for Disease Control and Prevention percentile charts for BMI (weight for height) specific for age and sex are a way to assess excessive weight gain relative to linear growth (American Academy of Pediatrics, Committee on Nutrition, 2003; Mitgutsch and Boardley, 2003).

Generally, once the child/adolescent has been identified as overweight/obese it is recommended to assess the family history, family patterns related to eating practices, current level of physical activity, and sedentary behaviors (i.e., TV, video games, and

computers) as well as evaluation for potential comorbidities (Ariza et al., 2004; Drohan, 2003). In addition, an assessment of the parents' attitudes regarding health and nutrition and their perception of their child's weight has been useful in the development of individualized family treatment interventions (Binns and Ariza, 2004; Hodges, 2003; Schwimmer, 2003).

It is suggested the approach to treatment include a combination of diet (decrease in caloric intake), exercise, behavior modification and education (American Academy of Pediatrics, Committee on Nutrition, 2003; Barlow and Dietz, 1998; St. Jeor et al., 2002) The Weight Realities Division of the Society for Nutrition Education, (2003), states the goal should be attaining a healthy weight, which is defined as the natural weight the body adopts given an adequate diet and significant levels of physical activity. A willingness to make a change, on the part of the child as well as the family, has been found to be effective in regards to weight loss and maintenance (Ariza et al., 2004; Barlow and Dietz, 1998; Drohan, 2002; Mitgutsch and Boardley, 2003; St. Jeor et al., 2002).

Unfortunately, the media, peers, childcare providers and the school system present challenges to children outside of the home. According to the American Academy of Pediatrics, Committee on Nutrition, (2003) and St. Jeor et al., (2002), there needs to be a concerted effort on the part of schools and communities to develop prevention and treatment programs to support gains made by family/clinician interventions.

Chapter 3 - Methods

Initial literature review after acceptance of the proposal consisted of journal articles that demonstrated the following: obesity as a growing problem for adolescents; methods for identifying obesity as a problem; and current treatment for obesity. Obesity and its comorbidities were the main focus of this literature review. Search engines included: CINAHL, Medline, Pub Med and utilizing keywords such as overweight, obesity, children and adolescents, BMI, type 2 diabetes.

The study design consisted of a retrospective chart review that looked at whether or not there was sufficient information to evaluate and diagnose obesity. In addition, if there was adequate information to make the diagnosis of obesity was it listed in the problem list, and if there was a diagnosis, was there an appropriate treatment plan implemented. In the beginning, permission was requested from the Institutional Review Board (IRB) to perform a retrospective chart review at 10-12 Family practice clinics in Northwest Ohio, with a goal to review at least 300 charts. Due to new HIPPA standards, permission was denied. The next step was to narrow the concept and permission was requested to conduct the study at the Medical College of Ohio (MCO) Family Practice Clinic with a goal to review 100 charts (see Appendix A). Permission was granted from Dr. Mark Weiner, and Dr. Sandra Puczynski on behalf of the MCO Family Practice Clinic (see Appendix B). The expeditious acceptance of the MCO IRB then followed (see Appendix C). In order for the patients to be included in the study, they had to have been seen in the clinic from April 30, 2002 – May 1, 2004. The ages of the male and female subjects ranged from 8-18 years. If the most recent visit included an up to date growth chart or weight and height documented in the flow sheet, age as of that visit was utilized.

If neither of these were available, age was documented from a prior visit when sufficient information to calculate BMI was recorded. All ethnicities were included. Based on the inclusion criteria the first 100 charts were pulled by the medical records department at the MCO Family Practice Clinic.

Data from the chart review was compiled based on the data-collecting tool (see Appendix D). Due to HIPPA standards, all the identifying information of the subjects in the study was kept in a locked file cabinet at the MCO Family Medical Practice clinic. In addition to the demographics, the number of charts that had adequate documentation regarding height and weight vs. those that did not were reported. In order to identify children and adolescents at risk for being overweight (BMI \geq 85th - <95th percentile) or overweight/obese (BMI \geq 95th percentile), a calculated BMI was obtained using the formula weight (lb) \div height (in²) x 703. The BMI was then plotted on an age-sex percentile chart (see Appendix E, and F).

The number of charts that had overweight/obesity listed as problem was also accounted for. In addition to the charts that had obesity listed as a problem, it was reported if the proper treatment was consistent with standard of care practices (diet, exercise, and behavior modification). The comorbidities associated with obesity in children and adolescents were also recorded

Chapter 4 - Results

Of the 100 subjects there were 54 females and 46 males. The ages of the subjects ranged from 8-18 years, with a mean age of 13 (see Figure 1). The sample population consisted of 33 Caucasians, 32 African Americans, and 35 other subjects where ethnicity was not documented (see Figure 2).

In reviewing the charts, there were 67 with an up to date growth chart, 28 with a growth chart but not up to date, and 5 without a growth chart at all (see Figure 3). Based on a calculated BMI, 44 out of 100 subjects were considered at risk for being overweight or were obese and the numbers of subjects considered to be of normal weight was 41. The number that could not be calculated due to insufficient data, specifically no height, was 15 (see Figure 4). The number of females with a BMI > 85th was 26 versus 18 males, and the mean age of the sample population diagnosed with obesity was 12.5 years. The prevalence of those at risk for being overweight or who were overweight/obese was highest among the undocumented ethnic population with 17, followed by 16 African Americans and 11 Caucasians.

Of the 44 subjects considered at risk for being overweight or who were overweight/obese, there were 19 that had the diagnosis of obesity. Of the 19 subjects, 11 of them had the diagnosis in the major problem list, and 8 had the diagnosis listed somewhere else other than the major problem list, such as in a progress note or well child examination form. The number of documented treatment plans referencing obesity was 9 of the 44 subjects and there were 6 of the 44 subjects that had a documented treatment plan when the diagnosis was not contained in the major problem list (see Figure 5).

The number that had overweight/obesity listed as a problem was 19 and of that, 13 had diet listed as a treatment; 3 had behavior modification listed as a treatment and 8 had exercise listed as a treatment. There were only 2 that had all three listed (see Figure 6). As mentioned previously, the number of patients considered at risk for being overweight or who were overweight/obese was 44 out of 100 and of that there were 3 that had a psychosocial comorbidity, listed.

Chapter 5 – Discussion and Conclusions

Initially, data was collected documenting the total percent of the randomly selected charts that had growth charts or height/weight, which may have been found on a flow sheet (i.e., vitals documented) or in a progress note. The height/weight ratio was used to calculate the BMI. Of the 100 subjects whose records were reviewed, 67 had up to date growth charts or adequate information to evaluate for overweight/obesity problems. Of the remaining 33 charts, 28 contained a growth chart but did have up to date information, and the remaining 5 charts did not have a growth chart at all.

It should also be noted the 15 of the 33 charts did not have adequate information, such as height and weight, located any where within the chart to determine BMI. There were 44 from the sample population that were considered at risk of overweight/obesity based on a calculated BMI.

Even though there was sufficient data within the chart to calculate and document overweight/obesity in the problem list this was not consistently being done. Only 11 of the 44 subjects that should have been considered overweight/obese had it documented in the major problem list. In addition, another 8 subjects listed overweight/obesity somewhere other than the major problem list (i.e., progress note, well-child examination form). Of the 19 patients with a diagnosis of overweight/obesity, there were 15 that had a treatment plan, consisting of one of the expected care practices (i.e., diet, exercise, or behavior modification). Only 2 had a treatment plan that was fully consistent with the standard of care practices, incorporating diet, behavior, and exercise.

The data from this study indicates that clinicians do not treat all children and adolescents diagnosed with obesity consistent with standard of care practices. There are

several studies that have concluded that the standard of care practice in the treatment of overweight/obesity in children and adolescents include reduction in the number of calories consumed (high-fat, and no nutritional value), increase exercise or activities of daily living (walking or riding a bike to school where appropriate), and behavior modification (decrease in sedentary activities, setting attainable goals) (American Academy of Pediatrics, Committee on Nutrition, 2003; Barlow and Dietz,1998; St. Jeor et al., 2002).

It has also been suggested that because the more serious affects of childhood obesity will not be seen until later in adulthood, the efforts to reverse the increasing epidemic of childhood obesity are lacking (Hill and Trowbridge, 1997). Data from this study demonstrates a problem with the ability of healthcare providers to reliably identify, diagnose and institute full appropriate treatment plans for obesity in children and adolescents. There are many studies that suggest that identification is an integral step in prevention of overweight/obesity (Dennison and Boyer, 2004; Fowler-Brown and Kahwati, 2004).

In conclusion, it is clear in this small sampling that the clinicians did not consistently identify and treat all children and adolescents with current standard of care practices regarding weight. It cannot be stressed enough that clinicians and their support staff need to take the time and make a more conscious effort to identify those children and adolescents at risk for being overweight or who are overweight/obese. Equally important is to make sure that clinicians and their support staff are educated about the comorbidities associated with obesity and the treatment options that are available.

One limitation of this study was having access to only one clinic; therefore the results may not be applicable to all primary care facilities. Another limitation was that the sample size was dependent on the number of patient charts available that met the inclusion criteria. This represented a compromise to the original project, which met roadblocks due to the new HIPPA standards. Time was also a factor, due to the fact the original premise of the study had to be changed and the focus narrowed.

Future research needs to focus on similar studies involving younger children, since it is documented that children as young as 4-6 years of age are more susceptible to adult obesity due to a period of early adipose rebound (Drohan, 2002; Whitaker et al., 1998). Standard guidelines need to be implemented for all primary care practices for documentation of height and weight so that BMI calculation can be done routinely not just at a well-child visit. The funds need to be allocated to have all primary care practices examine their own efforts regarding this epidemic as well as appointing someone to monitor the implementation of identifying those at risk, so that children who might come in just for an acute visit do not fall through the cracks.

It is almost impossible to ignore the growing problem of obesity in children and adolescents. It has been discussed everywhere from the Today show, to respected medical journals, to radio broadcasts, to media advertisements pushing fat-free/low carbohydrate diets (i.e., Atkins, South Beach) to fast food chains serving salads. So, who is to blame? All clinicians, family members, schools, media, government and most importantly the patient themselves, need to take personal responsibility for their health.

Due to our socialization or stigma regarding overweight issues, the subject is a difficult one to approach with patients, particularly perhaps for children and adolescents.

However, the time is now for physician assistants to demonstrate to patients that we are not only concerned about treating their hypercholesterolemia, and diabetes but also treating their issues regarding their weight.

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Figure 1: Age and Gender Distribution

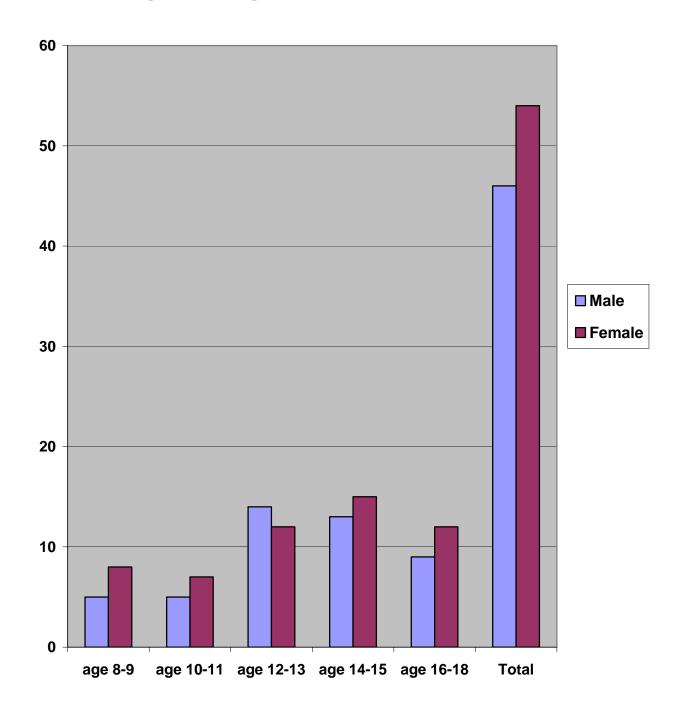


Figure 2: Ethnic Distribution

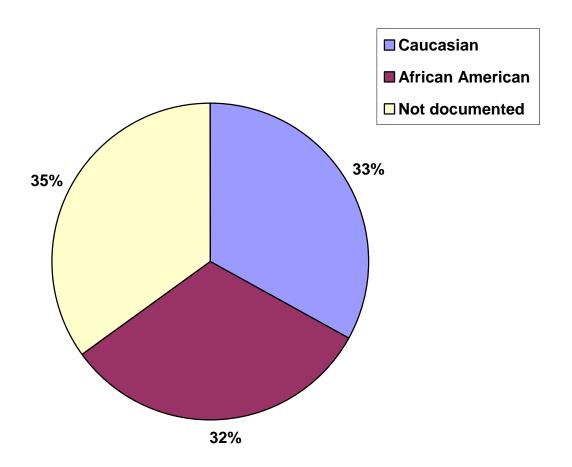


Figure 3: Presence of a Growth Chart

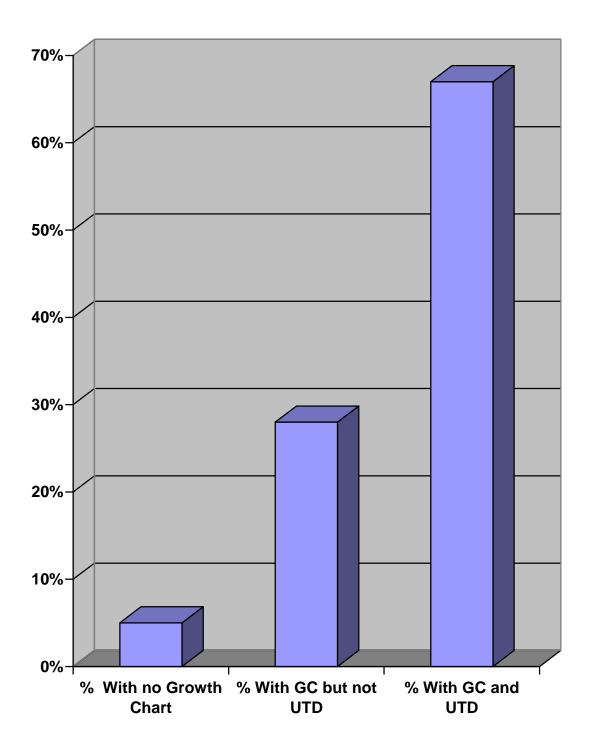
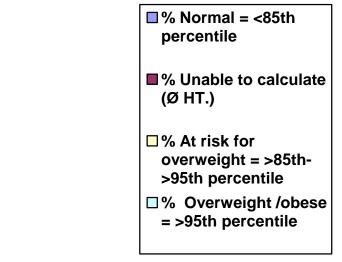


Figure 4: Distribution based on BMI



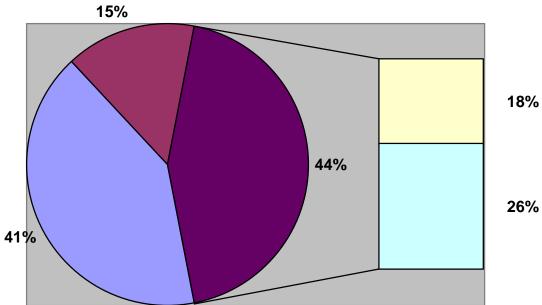


Figure 5: Overweight in the problem list and referenced treatment plan

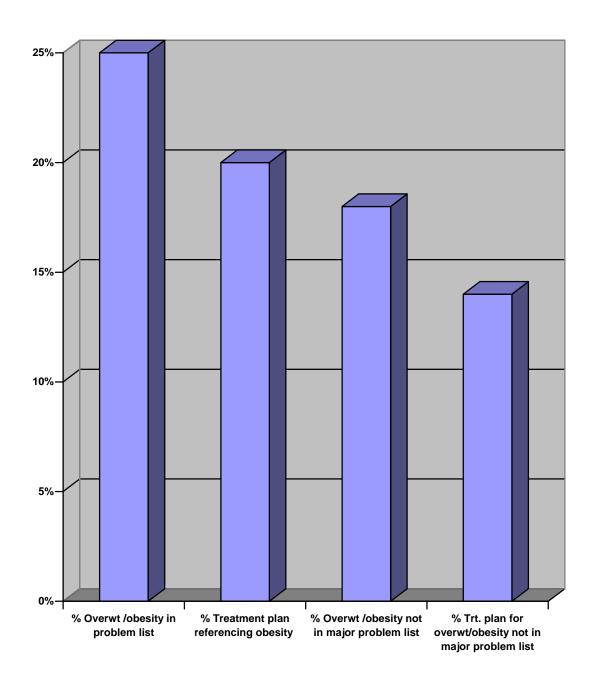
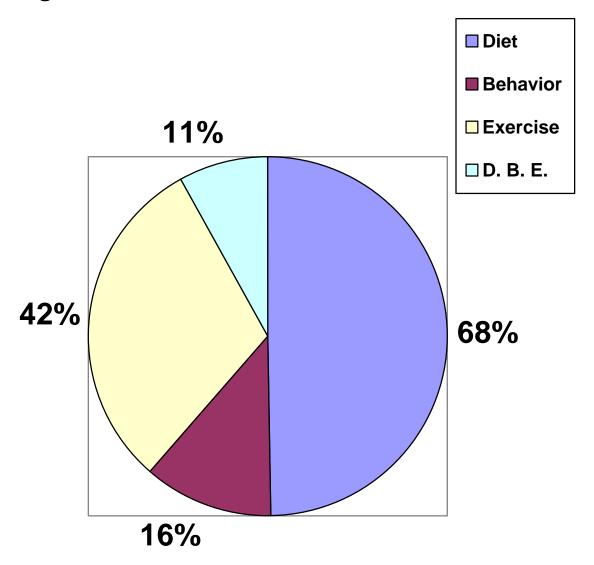


Figure 6: Standard of Care Practices



Appendix A: Letter requesting permission

Gail Evans, PA-S II 419.360.0292 gevans@mco.edu

Family Medicine Research Committee Medical College of Ohio Toledo, Ohio, 43614

April 22, 2004

Dear Family Medicine Research Committee:

My name is Gail Evans and I am a second year Physician Assistant student at the Medical College of Ohio. I am writing to request your clinics participation in my research.

As you are all aware, obesity in this country is an increasing epidemic. I am attempting to look at incidence of obesity in children and adolescents age 8-18 years old. The design of the project would be to conduct a retrospective chart review and the information obtained would not include any identifiers.

My advisor, Professor Martin Keck, discussed my research with Dr. Weiner and he asked that I send a resume and the protocol of my research to be reviewed for the committees' approval.

I appreciate your time and consideration in regards to this matter. If you should have any questions, please do not hesitate to contact me at 419.360.0292 or via email gevans@mco.edu

Sincerely,

Gail Evans

Appendix B: Acceptance letter from Dr. Weiner

Department of Family Medicine

Medical College of Ohio Garden Lake Building 1015 Garden Lake Pkwy. Toledo, Ohio 43614



Phone (419) 383-5519 Fax (419) 382-7876

Martin D. Keck, PA-C, M.Ed., MHS Academic Coordinator and Assistant Professor Department of Physician Assistant Studies Medical College of Ohio 3015 Arlington Avenue Toledo, OH 43614-5803

Dear Mr. Keck:

This letter is intended to confirm my interest in serving as a co-investigator for your study "Obesity in Adolescence." Your research protocol was reviewed and approved by the Department of Family Medicine faculty. We appreciate the value in reviewing our current practices for assessing children and adolescents for overweight and obesity. I will assist you and your student, Ms. Gail Evens in carrying this study out at the MCO Family Practice Center.

Sincerely,

Mark Weiner, D.O.

Assistant Professor of Family Medicine

Appendix C: IRB approval letter

Medical College of Obio INSTITUTIONAL REVIEW BOARD

MEMORANDUM

TO:

Martin Keck, PA, M.Ed.

Department of Allied Health/Physician Assistant Studies

MCO

FROM:

Eric Schaub, M.D. Zue Schaul

Chair, Institutional Review Board Research and Grants Administration

DATE:

May 18, 2004

SUBJECT:

IRB #104711- Obesity in Adolescence: An Epidemic in the Face of Modern

Medicine

The above project was reviewed and approved by the Chair of the Medical College of Ohio Institutional Review Board as an expedited review (category #5). This includes review and approval of the data collection tool. The requirement to obtain informed consent and/or authorization for use and disclosure of protected health information form has been waived, as this research does not include the collection of identifiable health information as defined by the HIPAA Privacy Rule. It was determined that this waiver for informed consent and authorization for use and disclosure of protected health information form at this site will not adversely affect the rights and welfare of the participants. This approval is in effect until the expiration date listed below, unless the IRB notifies you otherwise. The full board will review this research at its meeting on 06/17/2004.

NOTE: ALL of the materials (data, documents, records, or specimens) to be utilized in this project must "have been collected, or will be collected solely for nonresearch purposes* (such as medical treatment or diagnosis)" [Expedited category description as revised, effective November 9, 1998]. (* MCO IRB emphasis)

All information - that which is pertinent to the research project <u>and</u> that which is incidental to the project - must be handled at all times in a manner to protect patient confidentiality and privacy.

APPROVAL DATE:

05/18/2004

EXPIRATION DATE:

05/17/2005

It is the Principal Investigator's (P.I.'s) responsibility to:

- Abide by all federal, state, and local laws and regulations; the MCO federal assurance and
 institutional policies for human subject research and protection of individually identifiable health
 information including those related to record keeping and be sure that all members of your research
 team have completed the required education in these areas.
- 2. Promptly notify the MCO IRB at (419) 383-4251 of any untoward incidents or unanticipated adverse events that develop in the course of your research. Please complete and submit RGA Form 317 for ALL SUCH REPORTS for this protocol. The Principal Investigator is also responsible for submitting to the MCO IRB reports of adverse events that occur at other sites conducting this study and for maintaining an up-to-date cumulative table of adverse events (RGA Form 316) and submitting it to the MCO IRB for each research project. The Principal Investigator is responsible for reporting adverse events to the appropriate federal agencies and the sponsor (when one exists).

- 3. Report <u>promptly</u> to the MCO IRB any deviations or violations from the MCO IRB approved protocol in accordance with the procedures outlined in RGA Form 309. In your report include the protocol number and title, the subject's initials/specimen identifier (as appropriate) and study I.D. number, date of the event, a brief description of the occurrence and a description of any corrective actions taken. The Principal Investigator is responsible for reporting deviations, violations and participant non-compliance to the appropriate federal agencies and the sponsor (when one exists) in accordance with federal regulations, institutional policy and any other legal agreements with these organizations.
- Obtain <u>prior MCO IRB review and approval</u> for changes in study personnel and for any and all changes/new information that may require additional information be provided to participants.
- 5. Report <u>promptly</u> to the MCO IRB, sponsor (if this is research is sponsored) and all other required federal and state agencies all new information affecting the risk/benefit ratio and obtain <u>prior MCO IRB approval</u> for any changes in the study documents that may be required by the new information.
- 6. Obtain <u>prior MCO IRB review and approval</u> for all modified <u>and/or</u> added incentives going to the P.I., study coordinator, other study personnel, and/or the institution. These incentives may be in the form of money or other items of value, including, but not limited to, equipment, such as computers, and intangibles, such as frequent flyer miles.
- 7. Promptly notify the MCO IRB; other required MCO committees, departments or individuals; the sponsor (if this is research is sponsored); and all other required federal and state agencies of all potential conflicts of interest before beginning this research and, during the course of this research report to these committees, individuals and agencies any changes that may affect conflict of interest for any of the study personnel. Prior MCO IRB approval must be obtained for any changes in the study documents that may be required by information related to conflict of interest or any changes in this information during the course of the research.
- 8. Promptly notify the MCO IRB of any changes in contracts, budgets, grants or other agreements with sponsors, agencies or individuals regarding the conduct of this research <u>before</u> initiating these changes. The IRB reserves the right to review these study related documents and changes to them to verify accuracy and consistency with regard to the research protocol in order to protect the rights and welfare of the study subjects. Changes in these documents that have the potential to affect the rights, welfare or willingness of the study subjects to participate in or continue to participate in this research and changes in subject documents (such as informed consent, assent or authorization for use and disclosure of protected health information forms, etc.) that are a result of these changes <u>must</u> be reviewed and approved by the MCO IRB <u>prior</u> to being instituted.

Additional Information:

- Other Required Review(s) or Approval(s)
 Review or approval by the MCO Institutional Review Board/Privacy Board does not take the place of any other review or approval required by the Medical College of Ohio, non-MCO performance sites, the government and/or the study sponsor.
- Required Procedure to Request Review and Approval for Changes/Updates to MCO IRB Approved Research:
 Please complete and submit the Request for Amendment/Changes/Updates (RGA Form 314

Please complete and submit the Request for Amendment/Changes/Updates (RGA Form 3.14 found at http://www.mco.edu/research/rga_frms/rga314.doc) with a copy of all materials relevant to the requested change (including consent/assent/authorization for use and disclosure of protected health information forms if applicable) with the changes underlined. If you are requesting review and approval of consent/assent/authorization for use and disclosure of protected health information forms, please attach a clean copy of the revised forms for the MCO IRB to stamp. Please remember that all changes and correspondence submitted to the MCO IRB (regardless if they are generated by a sponsor, the P.I. or requested by the MCO IRB) must be in writing, signed and dated by the Principal Investigator.

Federally Mandated Continuing Review: MCO IRB protocols must be reviewed and reapproved not less than once per year. Research and Grants Administration will try to remind you when reapproval is due. However, it is the responsibility of the Principal Investigator to have his/her own reminder system in place to initiate the re-approval process at least a month prior to the expiration date shown above. Please note that Federal Regulations prohibit the extension of this expiration date. Please see the Application for Continuing Review (RGA Form 319 found at http://www.mco.edu/research/rga_frms/rga319.doc) for items required for continuing review.

> Required Final Report Upon Termination of Research:
When you decide to stop this research, you are responsible for completing and submitting a Final Report (RGA Form 320 found at < http://www.mco.edu/rescarch/rga_frms/rga320.doc>) to the

EAS/jw

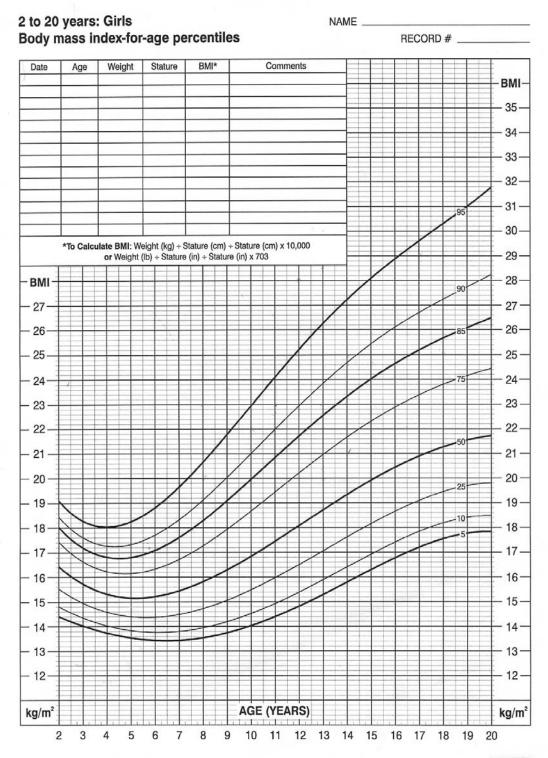
DHHS MPA # M-1358

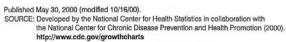
IRB #_____

Appendix D: Data screening tool.

		IRB #				
			#	(<u>of 100)</u>		
				Martin Keck / P.I. Gail Evans / S.I.		
DATA SCRE	ENING TOOL			Gail Evalls / S.I.		
Age:						
Gender:						
Ethnicity:						
Height:						
Weight:						
Growth Chart	No Y	es (but not up to o	date)Yes (and	up to date)		
Calculated BM	I Formula = Weig	ght in kg divided b	y height in meters so	quared), age & sex		
	(BMI Calculated	1)				
• •	• o =th					
Norma	ll - <85 th percentil	le for age and sex th percentile for ag	a and cav			
Obese	- >95 th percentile	for age and sex	e and sex			
	-	_	A) 01			
		•	3) Obese			
If #2 or #3 is c		_	ity listed in the probl	em list		
	_	No Yes				
If yes, is there	a documented tre	atment plan refere	encing the Obesity do	ocumented in the		
problem list?	_	No Yes				
If there is a tre	atment plan, is it	appropriate per St	andard of Care pract	ice including:		
Diet		No Yes				
Behavior	_	No Yes				
Exercise		No Yes				
Co-morbidities	s (HTN, Diabetes	, orthopedic probl	ems)			
HTN	D	iabetes	_			
Orthopedic	(specify _)			
Vascular Dz	R	enal Dz				
Psychosocial (Depression and/o	r Anxiety)				

Appendix E – CDC published Body mass index – girls ages 2-20

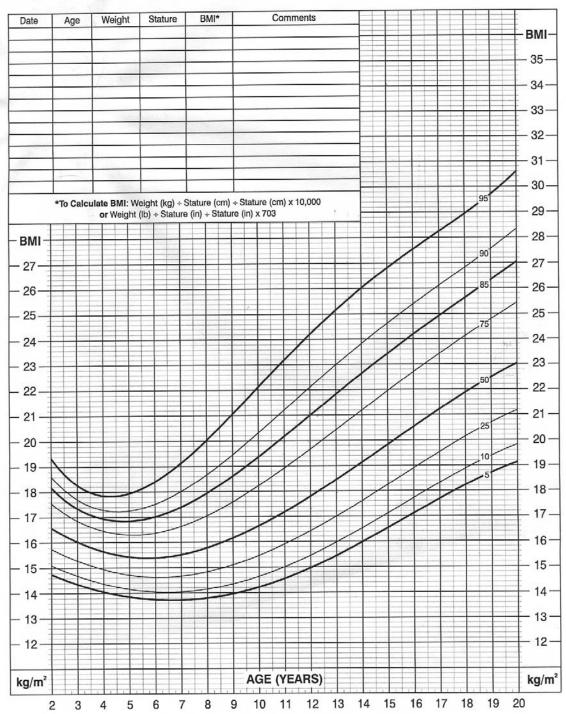






Appendix F - CDC published Body mass index - boys ages 2-20

2 to 20 years: Boys Body mass index-for-age percentiles NAME RECORD



Published May 30, 2000 (modified 10/16/00).
SOURCE: Developed by the National Center for Health Statistics in collaboration with
the National Center for Chronic Disease Prevention and Health Promotion (2000).
http://www.cdc.gov/growthcharts



Abstract.

Objective. The goal of this study was to assess the current level of identification of obese children and adolescents in the Primary Care setting and to evaluate the appropriateness of the treatment plan in accordance with current standard of care practices. **Methods**. A retrospective review of 100 randomly selected charts of children and adolescents ages 8-18 was conducted. Children and adolescents at risk as overweight/obese were identified and treatment plans were evaluated for comprehensiveness. **Results**. The total percent of children and adolescents considered at risk as overweight/obese was 44%. In the sample population the mean age diagnosed with obesity was 12.5 years. **Conclusion**. It is clear that clinicians are not doing enough to identify those at risk. The treatment of those diagnosed with obesity was not found to be comprehensive.