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14. ABSTRACT

In recognition that reduction in the incidence of diabetes and alleviation of its complications have become national public health priorities, the UPMC galvanized a partnership that included UPMC, Children's Hospital of Pittsburgh, University of Pittsburgh Diabetes Institute, and the United States Air Force Surgeon General's Modernization Directorate, to determine the best methods for preventing diabetes and improving diabetes care in both the civilian and military populations. The focus of this initiative was two-fold. Focus area one included establishing pediatric diabetes prevention and treatment programs. Specifically, we developed and implemented (1) an evidence-based pediatric weight management program to help youth and families in Pennsylvania and in the Air Force adopt a healthy lifestyle in order to maintain and achieve a healthy weight and (2) a pediatric diabetes education program for WHMC to improve diabetes care. Focus area two efforts included the evaluation of screening methods that are easily implemented by local practitioners and available to people with diabetes. For this particular award, previously demonstrated efficacy and use of digital fundus exams and educational programs were extended to WHMC. Educational programs consisted of updating health care providers in the most recent recommendations for the treatment of diabetic retinopathy, and screening components consists of technical run digital retinal photoscreening exams at WHMC. For both focus areas emphasis was placed on the development of scientifically-sound methodologies. The work accomplished through this award formed the basis of subsequent efforts to develop sustainable models of diabetes prevention and treatment.

15. SUBJECT TERMS Diabetes, Prevention, Community Partnership, Lifestyle Interventions, Self-Management Education, Quality Outcomes, Telemedicine, Children, Pediatrics, Joslin Vision Network

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1. INTRODUCTION

In recognition that reduction in the incidence of diabetes and alleviation of its complications have become national public health priorities, the University of Pittsburgh Medical Center (UPMC) galvanized a partnership that included the, Children's Hospital of Pittsburgh of UPMC (CHP), University of Pittsburgh Diabetes Institute (UPDI), and the United States Air Force Surgeon General's Modernization Directorate (US AF SGR-M), to determine the best methods for preventing diabetes and improving diabetes care in both the civilian and military populations. The focus of the project was to develop, implement and evaluate pediatric diabetes prevention and treatment programs and expand upon the Diabetic Image Reading Center through the implementation and deployment of Joslin Vision Network (JVN)and at Wilford Hall Medical Center (WHMC). Emphasis for the pediatric and retinal imaging efforts were placed on the development of scientifically-sound methodologies and process implementation, respectively. Our rationale was that evidenced-based prevention and treatment strategies are needed to prevent and/or delay diabetes and its complications in high-risk populations. The purpose of this report is to describe research accomplishments associated with completion of the project.

2. BODY

2.1 PEDIATRIC DIABETES PREVENTION AND TREATMENT PROGRAMS IN WESTERN PENNSYLVANIA

Pediatric obesity is a public health concern. Nearly one-third of American children are overweight or obese (1). There is a strong link between obesity and type 2 diabetes and other significant health problems such as cardiovascular disease and sleep apnea (2). The probability of childhood obesity persisting into adulthood is estimated to increase from approximately 20% at 4 years of age to approximately 80% by adolescence (3). It is probable that co-morbidities will persist in adulthood as well (4).

Obesity and its related health complications put a significant burden on the health care system. The economic cost of childhood obesity-associated illnesses has increased from 35 to 127 million dollars in the last two decades (5). Based on current trends, the prevalence of pediatric obesity with double by 2030 (6). It is estimated that health care costs attributable to obesity will exceed 860 billion dollars, accounting for 16% of total US health care costs (6).

Physician-supervised family-based cognitive behavioral lifestyle intervention for weight management that use clinically proven and scientifically-tested approaches have shown treatment approaches for pediatric obesity may be effective in short-term (7). However, long-term data for successful treatment approaches are limited. Therefore, CHP took the leadership role in the prevention and early recognition of pediatric obesity and type 2 diabetes mellitus.

This section describes research accomplishments related to Focus Area 1, Goals 1 – 3:

- **Goal 1:** Recruitment of key personnel to support the Weight Management and Wellness Center (WMWC) at CHP.
- **Goal 2**: Design, deliver and evaluate clinical operations and the Healthy Lifestyle Intervention Program.
- **Goal 3**: Deliver the Healthy Lifestyle Intervention Program to an underserved community.

2.1.1 CHP's Pediatric Weight Management and Wellness Program

CHP established a weight management and wellness program to tackle the serious problem of childhood obesity. The WMWC's clinical mission is to help children adopt a healthy lifestyle in order to achieve and maintain a healthy weight. Another very important mission of the WMWC is to screen and identify pre diabetes and diabetes in high risk children, as well as diagnose and treat obesity-related co-morbidities such as hypertension and polycystic ovary syndrome. The WMWC also has three principal research objectives: 1) to establish a Research Registry to store, track, and evaluate all clinical and other information obtained from patients; 2) to determine the prevalence of obesity-related illnesses, particularly pre diabetes and diabetes, and identify typical and novel risk factors for obesity-related illnesses among obese children; and 3) to determine the impact of a clinically administered pragmatic multidisciplinary, longitudinal weight management program upon body weight, obesity-related illnesses, and disease risk factors among obese children.

We developed a multidisciplinary outpatient model for the care of obese children that includes assessment and treatment of obesity and obesity-related illnesses (Table 1). Patient care is provided in a state-of-the-art facility with 9 exam rooms and a waiting area, all designed to accommodate the special needs of obese children. The WMWC patient population includes children and youth of either sex and any race or ethnic background, aged 0 – 21 years, with a body mass index (BMI) $\geq 85^{th}$ percentile for age and sex. Primary care providers refer patients to the WMWC if the child has a BMI > 95th percentile or $\geq 85^{th}$ percentile with weight-related health condition or disorder (i.e., hypertension, dyslipidemia, polycystic ovary syndrome).

Table 1. WMWC Treatment Protocol

Initial Visits (2-2.5 hours)
1. **Medical Assessment** The overall purpose of the medical assessment is to identify any medical or psychological co-morbidities of obesity, identify key habits related to obesity, and make an overall assessment of each child's (and family's) motivation to lose weight and resources available for the weight management effort. Specific elements of the medical assessment include the following: • Past medical and surgical history • Family history of obesity-related illnesses • Principal obesity-related habits (sweet beverage consumption, fast food, media time, family dining habits, and habitual physical activity) • Developmental history • Review of systems • Physical exam with focus on identifying obesity-related signs (e.g., acanthosis nigricans) • Routine laboratory testing: ▪ Fasting glucose or oral glucose tolerance test (Screening for diabetes) ▪ Fasting lipid profile (Sever hyperlipidemia in older children is treated with medication. For others, the presence of hyperlipidemia is presented to families as another motivation to lose weight.) ▪ BUN/Creatinine (Routine test of renal function) ▪ Dipstick urinalysis (Routine screening for proteinuria and urinary glucose)

- AST, ALT (Screening for non-alcoholic fatty liver disease)

The medical assessment follows closely the recommendations of the American Medical Association's Expert Committee on Identification, Assessment, and Treatment of Child and Adolescent Overweight and Obesity, of which Dr. Rao is a member. The screening procedures are based on the American Diabetes Association Consensus (8) of which Dr. Arslanian was one of six participating pediatric endocrinologists. The treatment of hypertension and dyslipidemia is based on the American Diabetes Association Consensus (9) of which Dr. Arslanian was one of the participating pediatric endocrinologists and cardiologists. There is little point in "customizing" this routine laboratory panel for individual patients. Almost all patients will have BMI > 95th percentile with one or more signs of insulin resistance and a family history of obesity-related problems. All the above tests, therefore, are justifiable since the vast majority of patients have multiple risks for obesity-related illnesses.

2. **Wellness Assessment**

The principal goal of the wellness assessment is to identify lifestyle habits contributing to obesity and to negotiate a written agreement with a family to change behaviors, incrementally over time. Specific components include:

- Identification of specific unhealthy dietary habits (e.g., frequent consumption of fast foods and/or soda drinks, breakfast skipping, eating large portions, etc.). A food frequency questionnaire is used for this purpose.
- Identification of current level and type of physical activity and sedentary behavior.
- Identification of motivation of child and family to make behavior changes in areas where they are most needed.
- Identification of perceived and tangible barriers to change.
- Negotiation of a Healthy Lifestyles Goals Agreement based on identified behaviors, child's preference for which behaviors to change, and parents' preference for which behaviors to change.

The underlying principles of the wellness recommendation are the following:

- The overall goal should always be promotion of healthy lifestyle habits. If habits become healthy, weight will take care of itself.
- Diets and other "quick fixes" are largely unsuccessful in children.
- Incremental behavior change in which children and families play a role in deciding which behaviors to change and how quickly is more likely to be successful than drastic behavior change.
- Behavioral or contingency contracting is an effective tool for changing patient behavior.

3. **Psychological Assessment**

The overall goal of the psychological assessment is to identify behavioral or psychological illness that may interfere with the weight management effort and to identify behavioral or psychological problems that are contributing to weight gain and address them if necessary.

Follow-Up Visits (45 minutes to 1 hour)
The routine periodicity of follow-up is every 2 months. Patients with significant co-morbidities may be seen more often. Highly successful patients may be seen less often. Follow-up by telephone and email is always available to all patients with wellness advisors, psychologists, and medical staff. The purpose of routine follow-up visits is the following: • Re-assessment of any medical co-morbidities and appropriate treatment and referral as is necessary. • Assessment of progress in meeting behavioral goals. Identification of reasons for failure to achieve goals, and re-negotiation of Healthy Lifestyle Goals Agreement as needed.

The WMWC is one of the first comprehensive, multidisciplinary, clinical pediatric obesity programs in the United States. It is by far the largest program of its kind in Pennsylvania and one of the largest in the United States. The WMWC has a full complement of highly trained personnel including the Director of the Center, who is a pediatric endocrinologist with expertise in type 2 diabetes and the metabolic complications of childhood obesity, the Clinical Director, who is a family practice physician with expertise in health education, additional pediatric endocrinologists, a physician assistant, clinical dietitians, behavioral psychologists, and exercise physiologists, as well community outreach professionals and support staff. The primary focus of the personnel is the clinical activity in the WMWC. Initially, we experienced some delays in hiring personnel, but since have refined our hiring strategies to fill and replace positions in a timely fashion. Based on experiences, we have also modified our staffing mix to optimize treatment provided in the weight management program. The WMWC team has treated more than 4,250 patients to date.

2.1.2. Research Registry

The Research Registry is a research database of medical information obtained from patients treated at the WMWC. The Research Registry was developed to track clinical course and outcomes of pediatric patients. As such, the Research Registry provides data on the effectiveness of obesity intervention and treatment strategies employed by the program. In addition, the Registry is used to perform retrospective research studies on childhood obesity and related conditions and identify patients who may be eligible for participation in future research studies.

Consent Process

All patients treated at the WMWC are offered participation in the Research Registry. Patients and their legal guardians are approached by a member of the clinic staff and asked to review a copy of the informed consent prior to their clinic visit. During the course of the visit, the attending physician reviews the informed consent form with patients and their legal guardians and addresses any questions or concerns prior to obtaining written informed consent for the Research Registry participation. By providing consent, patients agree to have their past, current, and future identifiable medical record information stored electronically in the Research Registry. They also provide their permission to be contacted for future research studies being conducted by clinic investigators. Patient names and identifying information are attached to a linkage code, which is stored in a secure location separate from the medical information. Access to the database is restricted to WMWC investigators and research staff.

Data Collection Process

The Research Registry is an IRB-approved database of de-indentified information on patients who are treated at WMWC and community practices. The process by which patient data is added to the Registry is detailed below.

- The Research Coordinator uses a Word-based table to track patients who were approached about the Registry and if they consented or not.
- At the end of each week the file is sent to the Registry data manager and data coordinator.
- The data coordinator takes the Word document and manually enters the patient data into the Registry database.
- Demographic information from the billing system is also entered into the Registry database by the data coordinator.
- A numbered code is assigned to each patient in order to de-identify the patient clinical information.
- The data coordinator produces a list each month from the scheduling system of all patients who visited the WMWC. This list is compared to the current patient list in the Registry to see who has had a return visit so that the clinical information can be found and updated.
- The data coordinator goes into the medical archive record system to get the clinical data for each visit.
- The data coordinator enters information from the medical archive system into the Registry.

Results of Data Analysis from the Research Registry

Enrollment for the Research Registry was initiated on 29 August 2006. The number of patients consented for participation is currently 2,184. Of the total number of participants, follow-up data is available for 1,053 patients.

Seventy percent (n=738) of children for whom we have follow-up data are making progress in terms of BMI percentile. In terms of weight loss, 41% (n=433) of patients have successfully lost weight during their care in the WMWC. Of those children who lost weight, 7% (n=74) were highly successful (i.e., $\geq$ 11 lbs in absolute weight) with a mean weight loss of 20.9 lbs (range = 11.1 lbs to 98.6 lbs). In addition, 222 children (21.1%) lost 2.2 to 11.0 lbs and 13% (n=137) lost up to 2.2 lbs. Additional results of data analysis from the Research Registry are shown in Table 2. Data on BMI, BMI percentile, percent body fat, and blood pressure are provided for all participants and sub categories, by age and gender. With the exception of systolic blood pressure for children less than 6 years of age, mean findings indicate improvement in all clinical outcomes listed.

Table 2. Results of Data Analysis from the Research Registry

Gender			
Female:	627	(59.5%)	
Male:	426	(40.5%)	
Age Distribution			
Under six years of age at initial visit:	85	(8.1%)	
Age six to 12 at initial visit:	510	(48.4%)	
Age > 12 (adolescents)	458	(43.5%)	
Mean age (years):	11 years and 3 months		
Initial Anthropometric Data			
Mean starting BMI, (N):	31.4 kg/m^2		(1052)
Mean starting BMI percentile, (N):	98.48		(1049)
Mean starting body fat %, (N):	40.14		(758)
Mean starting fat mass, (N):	31.0 kg		(758)
Mean starting systolic BP, (N):	109.8 mm Hg		(944)
Mean starting diastolic BP, (N):	67.8 mm Hg		(944)
Follow-up Anthropometric Data:			
Mean duration of follow-up (months):	5.45		
Mean change in BMI (kg/m^2):	-**0.13**		
Mean change in BMI percentile:	-**0.43**		
Mean change in body fat %):	**-2.09**		
Mean change in systolic BP (mm Hg):	**-0.78**		
Mean change in diastolic BP (mm Hg):	**-1.48**		
Sub-set Data			
Children age < 6 years			
Mean starting BMI, (N):	25.0 kg/m^2		(85)
Mean starting BMI percentile, (N):	99.6		(85)
Mean starting body fat %, (N):	31.6		(29)
Mean starting fat mass, (N):	10.3 kg		(29)
Mean starting systolic BP, (N):	97.7 mm Hg		(71)
Mean starting diastolic BP, (N):	61.0 mm Hg		(71)
Mean duration of follow-up (months):	5.4		
Mean change in BMI (kg/m^2):	-**0.22**		
Mean change in BMI percentile:	-**0.31**		
Mean change in systolic BP (mm Hg):	**+**1.54		
Mean change in diastolic BP (mm Hg):	-**0.35**		
Children ages 6 – 12 years			
Mean starting BMI, (N):	28.8 kg/m^2		(510)
Mean starting BMI percentile, (N):	98.5		(509)
Mean starting body fat %, (N):	39.4		(394)
Mean starting fat mass, (N):	24.1 kg		(394)
Mean starting systolic BP, (N):	107.8 mm Hg		(469)
Mean starting diastolic BP, (N):	66.4 mm Hg		(469)
Mean duration of follow-up (months):	5.8		
Mean change in BMI (kg/m^2):	-**0.09**		

Mean change in BMI percentile:	-**0.53**	
Mean change in systolic BP (mm Hg):	-**0.53**	
Mean change in diastolic BP (mm Hg):	-**1.62**	
Children > 12 (adolescents)		
Mean starting BMI, (N):	35.5 kg/m^2	(458)
Mean starting BMI percentile, (N):	98.2	(456)
Mean starting body fat %, (N):	41.7	(336)
Mean starting fat mass, (N):	40.9 kg	(336)
Mean starting systolic BP, (N):	114.3 mm Hg	(405)
Mean starting diastolic BP, (N):	70.5 mm Hg	(405)
Mean duration of follow-up (months):	5.0	
Mean change in BMI (kg/m^2):	-**0.15**	
Mean change in BMI percentile:	-**0.34**	
Mean change in systolic BP (mm Hg):	-**1.11**	
Mean change in diastolic BP (mm Hg):	-**1.26**	
Girls		
Mean age:	11 years 3 months	
Mean starting BMI, (N):	31.2 kg/m^2	(627)
Mean starting BMI percentile, (N):	98.3	(624)
Mean starting body fat %, (N):	39.5	(461)
Mean starting fat mass, (N):	30.2 kg	(461)
Mean starting systolic BP, (N):	108.4 mm Hg	(561)
Mean starting diastolic BP, (N):	67.0 mm Hg	(561)
Mean duration of follow-up (months):	5.4	
Mean change in BMI (kg/m^2):	-**0.07**	
Mean change in BMI percentile:	-**0.48**	
Mean change in systolic BP (mm Hg):	-**0.52**	
Mean change in diastolic BP (mm Hg):	-**0.91**	
Boys		
Mean age:	11 years 3 months	
Mean starting BMI, (N):	31.8 kg/m^2	(426)
Mean starting BMI percentile, (N):	96.7	(426)
Mean starting body fat %, (N):	41.1	(298)
Mean starting fat mass, (N):	32.2 kg	(298)
Mean starting systolic BP, (N):	111.9 mm Hg	(384)
Mean starting diastolic BP, (N):	68.9 mm Hg	(384)
Mean duration of follow-up (months):	5.5	
Mean change in BMI (kg/m^2):	-**0.21**	
Mean change in BMI percentile:	-**0.35**	
Mean change in systolic BP (mm Hg):	-**0.80**	
Mean change in diastolic BP (mm Hg):	-**2.04**	

Results of Data Analysis from Research Registry Regarding Rural Communities

Children in underserved communities may not have access to preventative care and lack the resources to travel to urban centers for treatment. CHP established a satellite WMWC in Johnstown, PA (Cambria County) through partnership with the *Pediatric Care Specialists* practice group. The satellite center provides all the services available through the main CHP WMWC to clients who prefer the Johnstown location. Dr. Goutham Rao, clinical director of the WMWC, along with other members of the wellness team (a dietitian and behavior therapist) treat patients at the Johnstown clinic one day a month. Patients treated at the satellite clinic are presented the opportunity to participate in the Research Registry.

We aimed to determine the impact of the weight management program in an underserved community by evaluating data included in the Research Registry for patients treated at the Johnstown clinic. During the 12 month period when this study was conducted, 46 patients were treated at the Johnstown clinic. Of those, 11 patients consented to participate in the Research Registry. Five participants were male and 6 were female with 2 females being of African-American descent. Mean age for the Cambria County patients was 11.67 years. Based on the data collected in the Registry, we are able to report that the mean BMI percentile decreased by -0.47 % from time of initial clinic visit to 6-month follow-up visit. This change indicates a decrease in body fatness. Although the decrease in BMI percentile is minimal, it is important to note that *weight maintenance* is a crucial first step towards weight loss. Thus, these preliminary results suggest that our program is having a positive impact on the health of our pediatric patients in this underserved community.

Evaluation of the impact of our weight management program in an underserved community was limited by the relatively few patients and families treated at the Johnstown clinic during the study period and the even smaller number of those who agreed to participate in the Research Registry. Interestingly, we have found that many families prefer to travel to the WMWC in Pittsburgh to seek weight management treatment even though our services have extended to the community. In fact, even after explaining to patient referrals living in the Johnstown area that a satellite facility is available to them, they still often choose to travel to the Pittsburgh clinic. Ideally, we would like to see community-based pediatricians adopt our program as a mechanism for educating and treating childhood obesity within their respective practices. We continue to work toward realizing this goal.

Clinicians have reported that patients and families seen at our rural site are less receptive to participating in the Research Registry than those treated at the WMWC. Furthermore, for patients treated at the WMWC, patients and families coming from rural regions are less likely to consent than their more urban counterparts. An assumption of extending the Research Registry to rural communities was that patients and families would be receptive to participating in the Research Registry.

Increasing receptivity to Research Registry participation in underserved communities and with rural-based patients is a challenging issue. One explanation for the discrepancy in participation between our rural site and the WMWC and between rural and urban families is familiarity with research studies. Families who regularly receive medical treatment at research-oriented hospitals and associated outpatient clinics are more likely to be familiar with the research environment and therefore more inclined to participate in research programs such as the Research Registry. According to the CHP Pediatric Clinical and Translational Research Center (PCTRC), many parents are anxious about their children participating in research studies and difficulty obtaining their consent for research participation is a common experience in pediatric clinical research. Literature on the consent process for pediatric

research studies indicates that reasons for nonparticipation in studies involving minimal risk (like the Research Registry) are not well understood. However, research suggests that full disclosure of the risks and benefits of study participation and a thorough understanding of research requirements increases the likelihood for participation. Thus, we may need to reexamine our informed consent forms and consent process to ensure that we are clearly communicating the purpose of the Research Registry and the associated benefits and risks for participation.

2.1.3 Healthy Lifestyles Intervention Program

Healthy Lifestyle Challenge, a family-centered, behavioral-based group intervention program was developed to serve as a supplement or alternative to one-on-one patient clinical treatment in the weight management program. Group-based programs have been shown to be an effective means of treating childhood obesity and a more cost-effective method than one-on-one treatment (10).

Initially, Healthy Lifestyle Challenge consisted of 16 sessions addressing obesity-related behaviors and was provided over the course of a year (Table 3). The sessions were constructed by a nutritionist, an exercise physiologist, and a behavioral health specialist. The material was given in lecture format, following PowerPoint slides. Each session split up the children from their parents mid-session and invited active participation by everyone. The program was tested at the WHWMC with two groups from March 2005 – February 2006 and June 2005 – May 2006, respectively. Ten children and their parents enrolled in Group 1 and 7 completed the program. Thirteen children and their parents enrolled in Group 2 and none completed the entire program. Neither group was screened for psychosocial barriers before being enrolled in the program.

After the initial testing, a clinical psychologist was hired at the WMWC. The clinical psychologist, along with a behavioral health specialist took the nutritional and exercise information from the Healthy Lifestyle Challenge and restructured it into a cognitive behavioral format. This new format was renamed Healthy Eating Routines and Optimal Exercising Styles (HEROES). The HEROES program was broken down into 28 sessions, which were provided over the course of one year and delivered in a chapter format versus PowerPoint (Table 3). In addition to in-person sessions, additional phone sessions were incorporated to minimize the commute to the WMWC. The HEROES program was tested at the WMWC from October 2006 to September 2007. Sixteen children and their parents enrolled in the program, but none completed the entire program.

Table 3. Healthy Lifestyle Challenge and HEROES Session Outlines

Healthy Lifestyle Challenge Sessions	HEROES
Weekly Sessions	*Weekly Sessions*
1. Welcome and Just Right!	1. Introduction
2. Lifelong Healthy Eating	2. Logging
3. Change Talk	3. Avoiding Food Traps
4. Healthy Shopping Skills	4. Healthy Eating
5. Planning Ahead	*Bi-weekly in-person with bi-weekly phone sessions*
6. Review of Nutrition Sessions	5. Praise Keeps Us Going
7. Energize Your Self	6. Healthful Eating Takes Planning/Healthy Breakfast & Lunches
8. Let's Get Active	7. Healthy Snacks, Dinners, & Drinks
Biweekly Sessions	8. Time to Get Physical/Increasing Physical Activity
9. Jumping Over Hurdles	9. Everyday Activities
10. Managing Emotions	10. Sedentary Activities
11. Coping with Teasing	11. Trying New Things
12. Review	12. Knocking Down Barriers
Monthly Sessions	13. Body Image and Self-Esteem
13. Activities	14. Going Out to Eat
14. Activities	15. Coping with Teasing
Quarterly Sessions	16. Staying on Track
15. Maintenance Plus	*Monthly in-person with monthly phone sessions*
16. Graduation Ceremony	17. Support from Family
	18. Social Support
	19. Am I Hungry?
	20. Special Occasions
	21. Managing Emotions/Avoiding Sneak Eating
	22. Keeping on Course to a Healthier Lifestyle
	23. Fad Diets – Do They Really Work?
	24. Making Progress
	25 – 28. Booster Sessions

Reasons stated for attrition included not wanting to travel to the WMWC (difficult to navigate, too far, tight finances), family scheduling conflicts, loss of motivation or feelings of frustration, and preference for individual treatment rather than group treatment. By far, the greatest reason for attrition was unwillingness to travel to the WMWC on a weekly or biweekly basis.

Low patient compliance to the group program was disappointing. However, reasons for attrition provided us with valuable information on ways to improve the structure of the program. Foremost, we realized we needed to make the program accessible to patients and families. Rather than having patients come to the WMWC, we needed to take the program to the community setting. In addition, the frequency and duration of the program needed to be altered. We reviewed the literature regarding successful group interventions and determined that a 12 week intervention was considered the most appropriate length for maintaining participant compliance.

We established a partnership with *Steps to a Healthier PA* in Fayette County, PA. This community organization approached our team to help them implement a group program in their community to

address pediatric obesity. We developed a marketing campaign and, for a 2-month period prior to the intervention, we advertised at schools, health fairs, and local physicians' offices as wells as through press releases distributed through CHP and local area newspapers. Despite our marketing efforts, only 3 children and their parents enrolled in the program. Due to limited interest, *Steps to a Healthier* PA decided to cancel the program at that time.

In addition, we established a partnership with the greater Pittsburgh YMCA program. A benefit of this relationship is that individual YMCA's can draw participants from their existing membership lists and recruit on-site. This relationship, we which further cultivated during FY06 efforts, has proven to be effective at improving youth and parent participation in the program. We also further refined our study procedures to foster participant compliance with the program.

2.2 PEDIATRIC DIABETES PREVENTION AND TREATMENT PROGRAMS AT WHMC

Pediatric obesity is also a concern for the military. The obesity epidemic is likely to affect the military most immediately as a result of dependent care for overweight or obese children. The potential future health care costs associated with pediatric obesity and its co-morbidities are staggering, prompting the surgeon general to predict that preventable morbidity and mortality associated with obesity may exceed those associated with cigarette smoking. An evidence-based intervention to prevent and treat pediatric overweight and obese military health care beneficiaries has the potential to improve the health and well-being of children and adolescents and reduce future health care costs for the military.

Increasing incidence of diabetes in Texas is a concern for WHMC given that it is a major treatment facility for military health care beneficiaries in the San Antonio, Texas catchment area. About one in every 400 to 600 Texas children and adolescents has type 1 diabetes (11). Based on 2002-2003 data, 3,700 youth were newly diagnosed with type 2 diabetes. The rate of new cases of type 2 diabetes among youth was 5.3 per 100,000 (12). Risk factors for type 2 diabetes include overweight and minimal or no physical activity. In 2004-2005, the prevalence of childhood obesity was greater in Texas than the national average. The overall prevalence of overweight and obesity in Texas schoolchildren was 42% for fourth-graders, 39% for eighth-graders and 36% for eleventh graders in 2004-2005 (13, 14). It has been projected that, if current trends in overweight and type 2 diabetes continue, persons born in the year 2000 will face a one in three chance of developing diabetes some time in their lives (15). These trends will certainly result in an increased demand for treatment and management by the medical community.

This section of the report describes research accomplishments related to Focus Area 1, Goals 4 – 6:

- **Goal 4**: Recruitment of pediatric clinical staff to build a plan for WHMC to participate in the CHP pediatric weight management and wellness project.
- **Goal 5**: Recruitment of pediatric diabetes educator to participate in the ADA recognized program at WHMC for diabetes education.
- **Goal 6**: Provide recommendation for a Center of Excellence at WHMC for pediatric diabetes

2.2.1 WHMC Weight Management and Wellness Program

To address the issue of pediatric obesity in the military population, CHP and the Air Force established a partnership to implement the CHP's evidenced-based model for weight management. The program

utilizes the family-based behavioral lifestyle intervention, counseling, and goal-setting strategies developed as part of the CHP WMWC's weight management program to implement therapeutic lifestyle changes in children and their families at WHMC.

Establishing the Weight Management Program at WHMC

To explore implementation of the weight management program at WHMC, a project team was formed that included CHP and WHMC project investigators and representatives of the Air Force and Surgeon General's Office. The project team held meetings to discuss the weight management program and to determine which components could be implemented at WHMC and what requirements needed to be addressed in order to realize implementation.

It was determined (13 November 2007) that the core components of the program - medical, wellness, and psychosocial assessments – would be implemented at WHMC by a wellness team through one-on-one visits with pediatric patients and their guardians. This goal would be met by following WMWC clinical protocols and procedures (Table 1), hiring appropriate clinical staff, and securing necessary equipment and facilities. An assessment of equipment and staff available at WHMC was made. Basic equipment (i.e., scale, stadiometer and blood pressure monitor) were already available; a Bod Pod (to measure body composition) needed to be purchased. It was determined that wellness staff would include a dietitian, behavioral therapist, medical assistant (LVN) and a physician assistant or nurse practitioner, the latter given dynamic military travel demands placed on active duty physicians. In addition, the decision was made that once personnel were hired, the staff would travel to Pittsburgh for training, which would include shadowing WMWC clinical staff during patient visits to become familiar with how assessments are conducted.

Significant efforts were made to engage clinical staff members and proved to be a very challenging and lengthy process. Staff members that were hired include the following individuals:

- Rayna Rogiers, Dietitian
- Brooke Wallace, Behavior Therapist
- Ernestina Ramirez, LVN
- Nadira Mangra, Nurse Practitioner

Clinic staff members were educated about clinical protocols and patient registration, scheduling, and charting procedures. Staff members, with the exception of Ms. Mangra, traveled to the CHP WMWC to learn about the weight management program. They met with WMWC staff, including Dr. Rao, the clinical director, and shadowed the wellness team during patient visits. Ms. Mangra will travel to Pittsburgh in the near future for further training.

An action plan was devised to facilitate implementation of the weight management program at WHMC. The action plan was followed to systematically address initial implementation requirements and to continue program development and expansion. Although the decision was made to implement the existing CHP WMWC clinical protocols and procedures, the project team had to address operational factors and requirements that were unique to the military, including the military's electronic medical record system and regulatory procedures.

The WHMC weight management program, now formally referred to as the SAMPC Pediatric Wellness Center, opened in November 2008. Since inception, the clinic staff has treated over 140 patients.

Needs Assessment

We conducted a population-based study to determine the prevalence of overweight and obesity among military pediatric healthcare beneficiaries in the San Antonio catchment area. Study findings were assessed and used to help determine the best approaches to recruiting participants into SAMPC Pediatric Wellness Center.

Project Manager Jodi Krall, on behalf of the UPMC project team, sought advice from their military partner, Lt. Col. Dale Ahrendt, on appropriate means for gathering data on the prevalence of pediatric overweight and obesity among military pediatric healthcare beneficiaries in the San Antonio catchment area. Lt. Col. Ahrendt reported that he was in the process of conducting a population-based study on pediatric obesity. He stated that the information he was gathering would be an appropriate source of data for our project.

Data were collected through chart review of 3,406 patients seen in June 2008 at the SAMMC Pediatrics North and South Campus Outpatient Clinics located at WHMC and BAMC. Patients were ages 2 to 23 years old with a median age 11.36 years. Of the 3,406 patients, 502 (14.7%) were overweight (BMI percentile > 85 but less than 95) and 455 (13.4%) were obese (BMI percentile > 95). The total overweight and obesity rate was 28.1%.

With a military pediatric healthcare beneficiary population estimated to be 35,000 in the San Antonio catchment area, these figures suggest that approximately 10,000 children and adolescents are eligible for participation in our weight management program (based on program eligibility criteria of BMI percentile > 85).

The prevalence of overweight and obesity among pediatric military healthcare beneficiaries in the San Antonio catchment area approximates national statistics. According to National Health and Nutrition Examination Survey (NHANES) data from 2003-2006, 31.9% of children and adolescents aged 2 to 19 years were overweight or obese in the US civilian, non-institutionalized population (16). These figures underscore the need for the SAMPC Pediatric Wellness Center to deliver weight management services and treat pediatric obesity in the military healthcare beneficiary population.

Approaches to Increase Clinic Referrals

Discussions were held among Lt. Col. Ahrendt, Col. Mary Pelszynski, Dr. Jodi Krall, Dr. Goutham Rao, and the SAMPC Pediatric Wellness Center staff to determine the best approach to recruit participants into our weight management program. We decided that given the percentage of patients eligible for participation in weight management program, the best method would be to work with primary care physicians to request patient referrals. This method would allow physicians to assess patients' need for our services and direct patients and families to our clinic. In turn, we set about designing approaches to promote and increase clinical referrals to the SAMPC Pediatric Wellness Center.

February 18-19, 2009, Jodi Krall and the SAMPC Pediatric Wellness Center staff met to discuss ways to increase clinical referrals to the Center. Feedback from WHMC providers/staff and patient referrals to date suggested that there was confusion and lack of knowledge regarding the Center's purpose, participation criteria, and referral system. Dr. Krall and the Center staff met with Captain Courtney Wallace, Element Leader of the WHMC Pediatric Outpatient Clinic, and Beverly Luce, a WHMC HR representative, to determine the best approach and forms for disseminating information. Captain

Wallace and Ms. Luce advised us to design an informational brochure describing the Center's purpose, scope of services, eligibility criteria, and referral process that could be provided to primary care providers. They also suggested we create a similar brochure that could be provided to referrals and families as well as distributed to provider waiting rooms and community programs. In addition, they suggested we develop a pocket card containing eligibility criteria that could be carried by physicians, residents, and nurses and serve as a quick resource for determining program participants. Captain Wallace and Ms. Luce envisioned the following process: Medical professionals (i.e., nurses and residents) would assess a patient's vitals and height and weight, the latter of which would be used to calculate BMI and BMI percentile. If the patient had a BMI percentile > 85 or presented an obesity-related medical condition (i.e., hypertension), the medical professionals could access the pocket card and determine if the patient met the eligibility criteria for our program. If the patient met the criteria, they would place the Center's informational brochure into the patient's medical chart so that the attending physician could review the program and refer the patient to us. Dr. Krall and the Center staff agreed that these suggestions would serve as beneficial approaches to increase clinical referrals.

Materials Development

Dr. Krall and the Center staff decided to use the informational sheet used to promote the WMWC at CHP as a starting point for a Center informational brochure. They modified the WMWC informational sheet so that it reflected the procedures, protocols, and contact information of the SAMPC Pediatric Wellness Center. In addition, they developed a pocket card for medical professionals. Realizing that the format and presentation of the content could be improved, they worked with the CHP marketing department to create a more professional version of the materials.

Marketing Plan

We devised a marketing plan to promote the SAMPC Pediatric Wellness Center and, in turn, increase clinical referrals. The plan was designed to be instated in phases through an iterative process based on provider, patient, and community program feedback. Feedback and referral rates will be used to guide future promotional efforts.

Phase I: Disseminate initial informational brochures to pediatricians and associated staff located at WHMC.

Phase II: Disseminate "professional quality" informational brochures and pocket cards to all primary care providers treating children and adolescents at WHMC and BAMC and provider waiting rooms.

Phase III: Disseminate "professional quality" informational brochures to community programs. We have already identified several programs located at the Lackland Air Force Base that are interested in promoting our Center.

In addition to systematic distribution of informational and promotional materials, we will periodically promote our services through health fairs, email announcements, and grand rounds. Already, we have attended two WHMC-based health fairs to promote our program. We plan to attend future health fairs and related events as we learn of them.

Our promotional efforts have been effective at increasing clinic referrals. In fact, the SAMPC Pediatric Wellness Center schedule is full. Promotional efforts also have improved provider and patient knowledge regarding referral criteria and the Center's mission and have resulted in fewer "no shows" for clinic appointments.

Exploring Collaboration with AETC "Fit for Fun" Program

Fit Factor (http://www.afgetfit.com/Home.aspx) is an Air Force-wide internet-based program designed to encourage youth and teens ages 6 to 18 years to improve their health and activity level and increase their awareness of and participation in Air Force programs and services. The program has an interactive component through which youth record their daily activities. Youth receive points for each activity; points can then be turned in for prizes. While Fit Factor is an Air Force-wide program, it includes base-level management, such that youth are able to identify and participate in base programs and retrieve prizes from a local source. Currently, Lackland Air Force base has 261 youth enrolled in Fit Factor with a goal of 521 participants.

Project Manager Jodi Krall contacted Steve Reichert, the Lackland Air Force base Fit Factor representative to investigate ways that our programs could collaborate. Mr. Reichert was very interested in having a face-to-face meeting and requested that we also meet with other Lackland base youth program representatives as well as the AF-wide Fit Factor representative, David Brittain

Dr. Krall met with the following individuals - Steve Reichert, Sports and Fitness Director; Reuben Rodriguez, Lackland Fit Factor Associate; Deb Wiley, Family Member Program Flight Chief; and Cynthia Mitchell, Health and Wellness Center (HAWC) Flight Commander. David Brittain was unable to attend. Dr. Krall provided program representatives with an overview of the SAMPC Pediatric Wellness Center mission and scope of services. In turn, program representatives described the services they offer – most of which are free of charge to military beneficiaries.

- Reuben Rodriguez reported that youth can sign up for Fit Factor via the Fit Factor Web site and use the site to learn how to become more involved with Lackland-based fitness activities.
- Deb Wiley explained that Family Member Program offers a variety of programs and services to military families, including child care, summer camps, child development services, and a youth center.
- Steve Reichert stated that there Lackland Fitness Centers are open to military families. In addition, the Sports and Fitness program staffs fitness trainers to work with youth and has a variety of sports leagues open to youth of various ages.
- Cynthia Mitchell said that the Health and Wellness Center offers numerous prevention classes and programs to educate military families on nutrition and diabetes. The HAWC is also responsible for the active duty fitness program. Furthermore, they are able to develop cooking classes for specific groups, such as parents or teens, as needed.
- Program representatives also reported that they affiliated with several other groups including 4-H, the Boys and Girls Club, and the Youth Sports Program.

The youth program representatives reported interest in establishing collaborative efforts with the SAMPC Pediatric Wellness Center. They stated that they may have the opportunity to use their program funds to support classes and interventions for our weight management program participants. Such efforts could include cooking classes or working fitness trainers. Collectively, we decided as a group to explore creating a "Passport to Programs on Base" to serve as a resource guide for youth.

Our quest to investigate collaborating with Fit Factor had a very fruitful outcome. Not only did we establish a relationship with Fit Factor representatives, but we learned of and established relationships with several other Lackland youth program representatives. This initial conversation, which resulted in

an exchange of program information and creation of potential ways to collaborate, also served as a jumping point for future outreach endeavors.

2.2.3 WHMC Pediatric Diabetes Education Program

Diabetes is a highly complex disease to manage, particularly for children and adolescents. Normal growth and development during early life and transition into adulthood are accompanied by a variety of physical and psychosocial changes, which command different standards of diabetes care than those required for adults (17). In addition, successful management of pediatric diabetes involves the entire family unit, requiring that parents and other caregivers understand their role in caring for their child's diabetes (17). The American Diabetes Association (ADA) recommends intense and ongoing diabetes self-management education (DSME) for patient and families as an effective means for properly managing diabetes, reducing diabetes-related hospitalizations and emergency room visits, and decreasing costs to the patient and provider (17-19).

ADA provides a DSME Recognition Program that assures uniform quality of services and offers the opportunity for Medicare and other third party reimbursement. UPMC in collaboration with UPDI has systematically developed a far-reaching network of DSME programs that has increased ADA Recognized Program sites from 3 in 2001 to 36 in 2009. Through its network, UPMC has demonstrated that DSME can sustain through reimbursement and can be delivered effectively in primary care. Air Force physicians and project leads recognized a need for DSME for pediatric diabetes patients at WHMC and joined forces with CHP to build a DSME program that complied with ADA standards.

Recruitment of a Pediatric Diabetes Educator

An ADA Recognition Program instructional team must include at least one member that is a Certified Diabetes Educator (CDE) or have recent didactic and experiential preparation in education and diabetes management. We successfully recruited a pediatric diabetes educator for WHMC who possesses all of these qualifications and comes to us with 30 years of diabetes education experience. Karen Poenisch, RD, LD, CDE, commenced activity as our pediatric diabetes educator at WHMC on 15 June 2009.

Enhancement of the WHMC Pediatric Diabetes Education Program

Ms. Poenisch worked with the Project Manager (Jodi Krall) and WHMC military clinicians (Lt. Col. David Paul and Major Ann Straight) to enhance the pediatric diabetes program provided to pediatric diabetic patients at WHMC. We followed criteria set forth by the ADA to ensure that the program meets their Recognition Program standards.

Table 4 lists the 10 National Standards for DSME, which are designed to define quality DSME and to assist diabetes educators in providing evidence-based education (20). The National Standards can be divided into the following 3 categories: Structure (Standards 1 – 4), Process (Standards 5 – 8), and Outcomes (Standards 9 – 10). Also listed in Table 4 are review criteria and indicators developed by the ADA Recognition Program to ensure that a DSME entity has systems in place to meet the national standards. The review criteria and indicators serve as benchmarks for ADA Recognition Program auditors when conducting reviews of DSME programs. In addition, the table includes descriptions of how the WHMC DSME program as an entity (Standards 1 – 4) and the pediatric DSME program specifically (Standards 5 – 10) have effectively addressed the National Standards.

Table 4. Application of ADA National Standards to the WHMC Pediatrics Diabetes Education Program

Standard	Review Criteria	Indicator(s)	WHMC Pediatric Diabetes Education Program
Standard #1 The DSME entity will have documentation of its organizational structure, mission statement, and goals and will recognize and support quality DSME as an integral component of diabetes care.	The DSME entity will have documentation that addresses its organizational structure, mission, goals and its relationship to the larger, sponsoring organization	• There is written evidence of the following: a. The organizational structure b. The mission of the program c. Mission-related goals. • There is evidence of organizational support and commitment to the DSME entity (e.g. Letter of support, participation of senior administrative personnel in the advisory process).	The DSME organizational structure, mission and mission-related goals were developed and documented when WHMC applied to the ADA recognition program in 2007.
Standard #2 The DSME entity shall appoint an advisory group to promote program quality. This group shall include representatives from the health professions, people with diabetes, the community and other stakeholders.	• An Advisory Group is appointed that is representative of the diabetes community and includes people affected by diabetes, health professionals, community members, and other stakeholders.	• A document exists (e.g. policy) which identifies members of the Advisory Group (members can fulfill multiple roles). At a minimum, the advisory group must include: a. Health professional(s) b. Person(s) affected by diabetes c. Community Member(s) • For single discipline staffed programs, the health professional member(s) of the advisory group must belong to a second discipline (e.g. different from the discipline of the program staff).	An Advisory Group, consisting of representatives of the diabetes community, promotes program quality. A pediatric representative (Karen Poenisch) will be added to the Advisory Group and will attend future meetings, including the next meeting to be held in September 2009.
	• Activities of the Advisory Group, reflecting its role as quality overseer are documented at least annually.	There shall be documentation of the activities, at least annually, which demonstrates how it contributed to the quality of the DSME. Members of the committee may contribute either as part of group meetings and/or be consulted on an individual basis (e.g. ballot,	Advisory Group activities are documented through meeting minutes.

Standard	Review Criteria	Indicator(s)	WHMC Pediatric Diabetes Education Program
		surveys, phone consults, emails).	
Standard #3 The DSME will determine the diabetes education needs of the target population(s) and identify resources necessary to meet these needs.	The target population/service community is identified and its needs assessed and/or re-assessed periodically.	• Documentation exists that reflects an assessment, at least annually, of the target population or service community and program resources, and identification of resources to address specific needs of the target population. This document must include: a. Target population/service community assessment (e.g. access, demographics, cultural influences, barriers to education). b. Assessment of program resources relative to services provided for the target population/service community (e.g. physical space, staffing, equipment). c. A plan to address the identified needs (e.g. identification of referral sources for additional services, plan for options for class times).	An initial assessment was made for the pediatric population based on San Antonio catchment area statistics and will be expanded upon with patient population data over the following year.
Standard #4 A coordinator will be designated to oversee the planning, implementation and evaluation of diabetes self-management education. The coordinator will have academic or experiential preparation in chronic disease care and education and in program management.	• The DSME entity has a designated coordinator.	There is documentation of one program coordinator.	Lois Wingate serves as the DSME coordinator.
	• The coordinator is academically or experientially prepared in areas of chronic disease care, patient education, and/or program management.	• Curriculum Vitae or resume of the coordinator reflects appropriate qualifications. • 15 hours/year of continuing education are required (if not a CDE or Board Certified-Advanced Diabetes Manager (BC-ADM)). Topics should include but are not limited to: chronic disease care, patient education and	Lois Wingate, RN, BSN, CDE, is qualified to serve as coordinator; her Curriculum Vitae reflects appropriate qualifications. Because she is a CDE, she is not required to meet the continuing education requirements.

Standard	Review Criteria	Indicator(s)	WHMC Pediatric Diabetes Education Program
		program management.	
	• The coordinator oversees the planning, implementation, and evaluation of the DSME.	Job description (or other document, e.g. performance appraisal tool) reflects requirements for chronic disease care, patient education and/or program management, and verifies the coordinator's responsibilities in planning, implementing, and evaluating the DSME.	Lois Wingate oversees the planning, implementation, and evaluation of the DSME.
Standard #5 DSME will be provided by one or more instructors. The instructor(s) will have recent educational and experiential preparation in education and diabetes management or will be a Certified Diabetes Educator. The instructor(s) will obtain regular continuing education in the field of diabetes management and education. At least one of the instructors will be a registered nurse, dietitian or pharmacist. A mechanism must be in place to ensure that the participant's needs are met, if those needs are outside of the instructor(s)'s scope of practice and expertise.	• The DSME instructor(s) must include at least one Registered Nurse (RN) OR one Registered Dietitian (RD) OR one pharmacist.	At least one RN or one RD or one pharmacist is involved as an instructor in the education of the participant.	Karen Poenisch was hired as the pediatric DSME project manager and serves an instructor for the DSME program. She is an RD and Licensed Dietitian (LD)
	• DSME instructor(s) must be qualified and provide diabetes education within each discipline's scope of practice.	• Instructor(s) must have valid, discipline-specific licenses and/or registrations. • Single Discipline Program: Instructor(s) must be CDE or have BC-ADM or accrue 20 hours/year of continuing education (CE) credits if practicing in a single discipline program. (CE topics must be diabetes-specific, diabetes-related, education or psychosocial, and relevant to services provided or population(s) served.) • Multiple Discipline Program: Instructors working in a multidisciplinary diabetes education setting (with other disciplines or instructional staff) can be CDE, BC-ADM, or accrue 15 hours/year of CE credits.	Karen S. Poenisch, RD, LD, is also a CDE who meets ADA recognition standards. She has extensive experience in pediatrics with regular multiple daily dose insulin and insulin pumps, as well as all other devices used in diabetes care. Although not a requirement since Ms. Poenisch is a CDE, she has had 20 continuing education hours each year in diabetes and will continue to earn 20 hours/year.
	• A mechanism must be in place to	• Guidelines (e.g. policy, procedure) must be in place for determining when patient	The psychiatric fellow is available to assess and

Standard	Review Criteria	Indicator(s)	WHMC Pediatric Diabetes Education Program
	meet the needs of participants if they cannot be met within the scope of practice of the instructor(s).	needs are outside of the scope of practice of single discipline program. • Communication to referring provider must include education not provided due to content being beyond the scope of practice of the specific discipline providing education.	provide psychosocial assessment and education. Karen Poenisch with the assistance of Dr. David Paul and Dr. Ann Straight, Pediatric Endocrinologists who serve as referring physicians, will determine when a patient should be referred to a psychiatric fellow. Ms. Poenisch will communicate patient's needs that require physician or psycho-social attention with follow-up charting.
Standard #6 A written curriculum reflecting current evidence and practice guidelines, with criteria for evaluating outcomes will serve as the framework for the DSME program. Assessed needs of the individual with pre-diabetes will determine which of the content area are to be provided.	• A written curriculum, with learning objectives and criteria for specifying methods of delivery and evaluating successful learning outcomes, is the framework for the DSME.	Validate that the education process is guided by a reference curriculum with learning objectives, methods of delivery and criteria for evaluating learning for the populations served (including pre-diabetes, diabetes type1, type 2, gestational diabetes mellitus or pregnancy complicated by diabetes) in the following 9 content area: a. Describing diabetes disease process and treatment options b. Incorporating nutritional management into lifestyle c. Incorporating physical activity into lifestyle d. Using medication safely and for maximum therapeutic effectiveness e. Monitoring blood glucose and other parameters and interpreting and using the	A reference curriculum with learning objectives, methods of delivery and criteria for evaluating learning for the population served (i.e. pediatric diabetes patients) for all 9 content area has been developed based on curriculum from two ADA-recognized programs (Children's Hospital of Pittsburgh of UPMC and Michigan Diabetes Research and Training Center) and tailored based on input from Drs. Paul and Straight to meet the needs of the

Standard	Review Criteria	Indicator(s)	WHMC Pediatric Diabetes Education Program
		results for self-management decision making f. Preventing, detecting, and treating acute complications. g. Preventing, detecting, and treating chronic complications. h. Developing personalized strategies to address psychosocial issues and concerns. i. Developing personalized strategies to promote health and behavior change (risk reduction)	pediatric diabetes patient population at WHMC.
	• There is periodic review and revisions of the curriculum and/or course materials to reflect current evidence.	There is documentation at least annually, of review and revisions as needed of the curriculum and/or course materials by DSME instructor(s) and/or advisory group. (For single discipline staffed program, advisory group must review curriculum and or course materials at least annually.)	A formal review and revision of curriculum and course materials to reflect current evidence will be made at least annually. Additional revisions will be made as needed and documented. The advisory group will review this curriculum annually.
Standard #7 An individual assessment and education plan will be developed collaboratively by the participant and instructor(s) to direct the selection of appropriate educational interventions and self-management support strategies. This assessment and education plan and the	• Participants receive a comprehensive assessment, including baseline Diabetes Self-Management knowledge and skills, and readiness for behavior change.	An assessment of the participant is performed in the following domains: clinical (diabetes and other pertinent clinical history), cognitive (diabetes self management skills, functional health literacy) and psychosocial and self care behaviors (support systems, lifestyle practices and behavior change potential) in preparation for education. Parts of the complete assessment may be deferred if applicable and the rationale for deferment documented.	A comprehensive assessment form has been developed to meet these requirements. In addition to the assessment, participants will complete a quiz to assess their knowledge of diabetes self-management.
	• Participants have	There is evidence of an ongoing education	Progress notes and goal

Standard	Review Criteria	Indicator(s)	WHMC Pediatric Diabetes Education Program
intervention and outcomes will be documented in the education record.	an education plan based on their individual assessment.	planning and behavioral goal-setting based on the assessed and/or re-assessed needs of the participant.	sheets will be used to document ongoing education planning and behavioral goal-setting based on participant assessment/re-assessment.
	• There is evaluation of the education plan after the educational intervention.	The DSME has a process for evaluating the educational intervention to determine success of the education plan, including evaluation of behavioral goal achievement.	Goal sheets include an evaluation section to determine and document success of the educational plan/intervention.
	• The education process is documented in the permanent record.	Documentation includes other evidence of the education process: referral from provider, assessments, education plan, with dates of implementation/interventions, learning outcomes and plans for follow-up as indicated.	Education process is documented with a flow sheet and noted in the patient's medical record; documentation includes listed criteria.
Standard #8 A personalized follow-up plan for on-going self-management support will be developed collaboratively by the participant and instructor(s). The patient's outcomes and goals, and the plan for on-going self-management support will be communicated to the referring provider.	Participants will have a plan for post education self-management support for ongoing diabetes self care beyond the formal self management education process.	• There must be evidence of a personalized follow-up for plan of Diabetes Self Management Support (DSMS) (e.g., return to referring provider, referral to support groups, referral to community programs, etc.). • There must be evidence of communication of the follow-up plan with the referring provider.	Progress notes provide evidence of personalized follow-up plans for DSME. Personalized follow-up plans are communicated to the referring provider through information charted in the medical record.
Standard #9 The DSME entity will measure attainment of patient-defined	Attainment of goals/outcomes shall be measured regularly in	• There is evidence of collection and summary of participant behavior goals used to evaluate the effectiveness of the DSME.	Attainment of goals/outcomes will be measured at regular intervals

Standard	Review Criteria	Indicator(s)	WHMC Pediatric Diabetes Education Program
goals and patient outcomes at regular intervals using appropriate measurement techniques to evaluate the effectiveness of the educational intervention.	order to evaluate the effectiveness of the educational intervention.	• There is evidence of a collection and summary of other outcomes (e.g. clinical, quality of life, process) to evaluate the effectiveness of the DSME.	and will include, but not be limited to, the following: • Glucose monitoring • Proper medication use • Appropriate growth and weight status • Hemoglobin A1C values • Assessment of patient and parental satisfaction
Standard #10 The DSME entity will measure the effectiveness of the education program and determine opportunities for improvement using a written continuous quality improvement (CQI) plan that describes and documents a systematic review of the programs' successes and outcome data.	• The DSME entity has a quality improvement process and plan in place for evaluating the education process and program outcomes.	There is documentation of a CQI plan/process (e.g. written policy, annual program plan, CQI meeting minutes).	Based on the initial assessment of our target population's needs, we have determined that parental deployment impacts diabetes self-management. Currently there is no formal diabetes education plan for the caregiver who remains when a spouse is deployed. This issue will serve as the focus of our first CQI process and plan.
	• Quality improvement projects are developed and implemented according to the plan.	There is documentation of at least one project following the quality improvement plan.	
	• Results are used to make improvements in the DSME.	There is evidence of application of the results of the quality improvement project to the DSME upon completion.	

Maintaining ADA Recognition

Recognition was granted on 24 May 2007 for WHMC DSME. Jan McWilliams, UPMC, received notice from ADA on 8 July 2009 stating that the pediatrics component could be added to the existing Recognized program at WHMC. ADA Recognition lasts for a 3-year period. If at time of renewal or any other time in the future it makes sense or we are requested by ADA to apply for Recognition as a separate program or as an extension site to the adult diabetes education program, we are prepared to do so. One rationale for separating the programs is that they serve different populations (i.e., adult versus pediatric) and, as such, have population-specific objectives including curriculums, behavioral goals, and quality improvement plans.

Requirements for Maintaining ADA Recognition

Annual Status Report

It is the responsibility of the program to maintain the National Standards for DSME and the Recognition program criteria at all times during the 3-year recognition period. The program coordinator is required to complete an on-line Annual Status Report during the anniversary month of the Recognition to confirm that the program continues to maintain National Standards. The coordinator receives email notification of when the Annual Status Report is due.

On-Site Audit

Five percent of all Recognized programs receive an on-site audit. The sites to be audited are selected randomly from among all programs currently Recognized. If a program is selected for an audit, materials used to support the application are reviewed during an on-site audit. Current materials to confirm that the program continues to meet the National Standards are required as well.

Recognition Renewal

Recognition must be renewed every three years. It is the responsibility of the program to know when Recognition will expire and to submit a timely application for renewal. ADA recommends that programs submit renewal applications at least 90 days prior to the current expiration date. For our program, Recognition will expire 24 May 2010. As such, we will submit our renewal application by 24 February 2010. According to the 7th Edition Education Recognition Application Instructions (www.diabetes.org/recognition/education), we are required to provide the following information:

- Applicant demographic information (name of sponsoring organization, name and address of administrative officer, and verification of support of applications)
- DSME coordinator information (contact information and written job description)
- DSME advisory group information (documentation of an advisory system and methods of advisory group involvement)
- Site information (site name, contact information, program participant information, service area (rural, urban, and/or suburban), type of setting (i.e., outpatient, hospital))
- Instructional staff information (total number and type of instructional staff)
- Reference curriculum
- Types of DSME methods (1:1 or Group) used in our program
- Verification that participant education records document the following information:
    - Referral from primary care provider
    - Comprehensive assessment
    - Education plan with participant selected behavioral objectives based on the assessed needs of the participant

    - Educational interventions, which include date of intervention, content taught, and name(s) of instructor(s)
    - Evaluation of progress towards behavioral goals and related health or quality of life outcomes and/or achievement of learning objectives
    - Communication with the referring provider, including plan for diabetes self-management support
- Participant individualized behavioral outcomes/objectives/goals
- Other participant outcomes (e.g., hemoglobin A1C, lipids, patient satisfaction)
- CQI process plans

Program Renewal Data Collection Requirements
Data period: Data collection on outcomes should be done on a continuous basis. However, the data period for applications is 3 months in duration and serves as a snapshot for outcomes data. Renewing programs may report outcomes collected over periods other than a 3 month data period. Outcomes data reported on the application should represent current operations – a year within the application submission date.

Participants: A total number of participants engaged in the DSME program during the data period must be 10 or more per site (except for expansion sites for which no minimum is required). Application should include:

- The average number of hours participants spent in DSME services
- Population served at the site during the data period
- Participant age, type of diabetes, race/ethnicity, any special needs, unique features to overcome, and barriers to learning

Each recognized program must track at least one behavioral objective as an outcome and one other program outcome, for a minimum of two program outcomes. Behavioral outcomes are grouped generally under the 7 self-care behaviors. Other outcomes include clinical outcomes (i.e., hemoglobin A1C, blood pressure, lipids), quality of life outcomes (i.e., lost work days, hypoglycemic events), and process outcomes (i.e., patient and physician satisfaction). Programs may report on as many outcomes tracked as they wish even though reporting is expected for at least one of each category (e.g., one behavioral and one other program outcome). Programs must also indicate achievement of outcomes. Target achievement is what degree of achievement is expected. This target is set based on knowledge of target population, national or regional standards, and/or effort put forth by program staff towards achieving this benchmark in terms of resources and capabilities of the program. Actual degree of achievement is what is assessed at the time of follow-up and includes data on only the patients that have successfully completed follow-up and have had follow-up outcome evaluation. Outcomes are currently reported in percentages on the application with options for 0%, 25%, 50%, 75%, and 100%.

Assessment of Diabetes Education Program: Patients' Need for and Patient, Parent, and Providers' Responses to the Program

We assessed patients' diabetes education needs through a diabetes self-management quiz, glycosylated hemoglobin (hemoglobin A1C) values, and qualitative assessment of factors influencing diabetes self-management. We gathered information about patient, parent, and provider acceptance/response to the pediatric diabetes education program through a satisfaction survey and written accounts, respectively.

Pediatric diabetes educator Karen Poenisch, RD, LD, CDE began seeing patients under direct supervision of Lt. Col. Paul and Major Straight on 10 August 2009. We collected baseline patient data through 31 August 2009. During this time period, Ms. Poenisch saw 32 pediatric patients (average age 14.6 years; age range 5 – 20 years; 12 males and 20 females) who participated in the diabetes education program to various degrees.

Patient Assessments

Diabetes Self-Management Knowledge Quiz

The American Association of Diabetes Educators identifies 7 self-care behaviors that are essential for successful and effective diabetes self-management; these behaviors are incorporated into the National Standards for DSME (20). The self-care behaviors include: 1) healthy eating; 2) being active; 3) monitoring; 4) taking medication; 5) problem solving; 6) healthy coping; and 7) reducing risks.

CDE Karen Poenisch developed a quiz to assess the diabetes self-management knowledge of patients seen at WHMC for pediatric diabetes. The quiz consisted of 28 items targeting the 7 self-care behaviors; some items encompassed multiple self-care behaviors. Quiz results help identify problem behaviors and are utilized to tailor diabetes self-management education.

Twenty-five patients completed the quiz prior to their visits with physicians and CDE. As shown in Table 5, the 7 self-care behaviors are ranked in descending ordered based on the number of survey items for each behavior divided by the number of incorrect answers for those items by patients. Results indicate that patients were least knowledgeable about 1) monitoring (blood glucose, ketones, etc), 2) being active, 3) taking medications, and 4) healthy eating.

Table 5. Results of Diabetes Self-Management Knowledge Quiz

Behavior	Number of Quiz Items	Incorrect Answers	
		Count	Percent
1. Monitoring (blood glucose, ketones)	6	33	22%
2. Being Active	1	5	20%
3. Taking Medications	2	9	18%
4. Healthy Eating	3	13	17%
5. Reducing Risks (acute and chronic complications and ER visits)	13	42	13%
6. Problem Solving	7	16	9%
7. Healthy Coping	2	4	8%

Hemoglobin A1C

Hemoglobin A1C levels reflect average blood glucose levels over several months and have strong predictive value for diabetes complications. The ADA recommends a goal A1C value between 7.5 and 8.5% for children <6 years old, ≤8% for children 6-12 years old, <7.5% for adolescents 13-19 years old, and <7.0% for adults (17).

For 32 patients seen during the baseline assessment period, the average A1C value was 9.44%, indicating need for improvement in glycemic control.

Factors Influencing Diabetes Self-Management

Many factors influence a child's ability to self-manage diabetes and experience optimal glycemic control. Based on qualitative information gathered during patient encounters, the following factors were identified as significant concerns or issues related to diabetes self-management.

- Lack of adherence to self-care: Patients who are frustrated or overwhelmed with diabetes and did not want or were unmotivated to practice self-care were likely to stop taking insulin or oral medication for type 2 diabetes, not test blood glucose or only test when they "feel poorly," not keep logs of blood glucose levels, not check ketones when blood glucose is high (running the risk of inappropriate treatment and diabetic ketoacidosis). Lack of adherence resulted in high blood glucose averages, multiple episodes of diabetic ketoacidosis that required hospitalization, and signs of diabetic kidney disease at a young age.
- Condition-related complications, including cystic fibrosis-related diabetes, multiple conditions (diabetes plus celiac or thyroid disease), and sexually active patients with uncontrolled diabetes (i.e., increased risk for pregnancy and birth defects).
- Psychosocial issues: Bipolar disorder, depression, eating disorders, running away from home, and suicide attempts.
- Lack of parental/family support: Lack of parental involvement in patient's diabetes care, parental deployment, or family issues such as divorce, deceased parents, and secondary caregivers who may not be involved or not very involved in the child's diabetes care.

<u>Patient and Parent Responses to Diabetes Education Program</u>

A post education survey was completed by patients and parents if significant education took place during the patient encounter. The survey consisted of 5 Likert-scaled items and 3 open-ended items to assess the patient/parents response to diabetes education. Notably, the CDE offered to have the patient turn in the survey to the physician or front desk but all wanted to give them to her directly, suggesting that they felt comfortable sharing their responses with the CDE.

Seven patients/parent dyads completed the post education survey. Of these patients, only 3 had previously seen a diabetes educator. As shown in Table 6, patients/parents provided favorable responses to the diabetes education encounters.

Table 6. Results of Post Education Survey

Likert-Scaled Items	Mean Score (100 points possible)
• If you have seen a diabetes educator before, how would you rate today's visit compared to previous experiences?	100
• Overall, how would you rate the diabetes education that you received today?	97
• How satisfied were you with the information given by the diabetes educator?	100
• How satisfied were you that the diabetes educator listened to you when you had questions to ask?	100

• How satisfied were you that the diabetes educator answered your questions in a way that you could understand?	97

Open-ended Items

1. If you had questions about diabetes education you wanted to ask but didn't, why?

- All questions that we had were asked and as other questions arise, we consult with the doctor and diabetes educator.
- All my questions were answered.
- I was comfortable to ask everything and the educator answered all of my concerns.

2. Was there anything about the diabetes education experience that you found particularly helpful?

- (I received) information that needed reinforcement from previous classes.
- Discussion about the Sure-T needle and scar tissue buildup.
- Insulin pump information was very helpful.
- She explained basal rate and was very helpful. I was extremely pleased with all information.
- The nutrition section was very helpful to me.
- The overall outlook on diabetes and the professional knowledge that we have gained from Karen and Dr. Paul have helped us a lot.
- Educator was thorough and provided brochures which help us to understand diabetes more.
- The carb count.

3. What diabetes care topics would you like to learn more about?

- How to deal with situations and try to teach my son how diabetes affects him when he doesn't eat right foods or sneaks candies. I believe the more education we get as parents or friends, the more support we can provide to those in need.
- Is it possible to figure out a correction factor for when he is low? Example: blood sugar is 60. Ingest 5 carbs?
- When we choose the insulin pump would like more training on the device.
- I would like more educational materials.

Provider Responses to Diabetes Education Program

Lt. Col. David Paul, MD, Pediatric and Adolescent Endocrinologist, WHMC

"Karen Poenisch came on board as a pediatric diabetes educator recently as the main person hired to establish a formal pediatric diabetes COE through the UPMC pediatric wellness and diabetes programs. Since her arrival, despite prolongation of the credentialing process, she has been a highly proactive initiator of multiple projects to improve the diabetes care here at Wilford Hall USAF Medical Center. In short, I have only excitement for Karen's future role in the care of children with diabetes here, and great appreciation for the hard work, time, and expertise she has already shown. She has clearly worked very diligently towards implementing and improving many aspects of diabetes care delivery and progress monitoring. I have a high degree of expectation that diabetes care here at Wilford Hall, BAMC, and Fort Hood will greatly improve specifically due to her presence here as a pediatric diabetes educator. I have seen her in action during numerous patient encounters and she clearly is an expert at all aspects of day to day management of diabetes in children."

Karen Poenisch, RD, LD, CDE, UPMC/WHMC

"I feel it is imperative to have a pediatric diabetes educator in this practice. Adult educators are not familiar with how to handle pediatric patients, in medication adjustment, supplies used, and the issues and problems patients have, even if they are well controlled. Then add all the issues listed above, just seen in one month, and it is an overwhelming need for as many hands on board as possible. I would like to involve the psychiatry program fellows in the future to see some of the more complicated

psychological issues. The physicians are excellent but they cannot see patients with problems of this magnitude without assistance. The diabetes educator also has the opportunity to bring more variety of help to patients with all the supplies and materials we find and use in teaching. Patients, school nurses, and parents have all been overwhelmingly pleased that we now have another resource on board to help them. The program still needs some development to make it into the program I envision, but we will get there and be very successful."

Following is a list of benefits of a diabetes educator to patients, parents, and providers.

- Establish relationships with vendors who then provide samples of product for patients to try
- Order materials and brochures for patients free of charge
- Communicate with school nurses about diabetes treatment for school-aged children. The CDE can contact the doctor regarding these problems and relay information or teach the nurse what to do in different situations.
- Develop medical management plans, which are long treatment plans required by schools yearly and followed by school nurse.
- Communicate information to parents on diabetes care.
- Track problem patients, providing one-on-one attention in attempt to lower their risk for acute and chronic complications
- Obtain treatment for hypoglycemia to be kept on the floor for timely administration.
- Obtain software to download meters and pumps especially when patients have no records and cannot get their hemoglobin A1C at the appointment.
- Train patients on how to use insulin pumps and glucose sensors.

Discussion

Major outcomes of the baseline assessment of pediatric diabetic patients and the diabetes education program are as follows:

- Patients have limited knowledge about diabetes self-care behaviors.
- Patients need improvement in glycemic control as indicated by elevated hemoglobin A1C values.
- Patients' ability to sufficiently manage their diabetes is influenced by limited knowledge, lack of motivation, existing health conditions, psychosocial issues, and lack of family support.
- Providers recognize the importance of having a diabetes educator on staff.
- Patients and parents were highly satisfied with the diabetes education they received as part of the new DSME program.

These findings emphasize the critical need to provide patients and parents with on-going, evidence-based diabetes education and support the following recommendations:

- Individualized goal setting and improvement in diabetes self-care behaviors are needed to attain target A1C levels, normalize blood glucose levels, prevent diabetes ketoacidosis and related hospitalizations, and reduce risk for acute and chronic complications.
- Patients and parents need guidance to acquire the necessary self-management knowledge and skills, develop the confidence to perform appropriate self-care behaviors, and develop the problem solving and coping skills to overcome barriers to self-care behaviors.

Baseline findings were limited by the small sample size of patients included in the assessment. We were prepared to offer diabetes education to all pediatric diabetes patients scheduled for visits at WHMC

during assessment period. However, an unanticipated challenge impeded our ability to fully meet our goal. Unbeknownst to our project team, WHMC requires that all health care professionals who must be credentialed (i.e., registered dietitians, nurse practitioners) provide direct patient care within 2 years of hire. Karen Poenisch did not meet this requirement as a dietitian and was consequently prohibited from providing unsupervised patient education. To fulfill the WHMC credentialing requirement, Ms. Poenisch must enroll in a volunteer's program during which she must demonstrate competencies in nutritional counseling. Upon learning this requirement, we aggressively attempted to enroll Ms. Poenisch in the program. After multiple attempts over the course of more than a month, Ms. Poenisch finally has an interview with the director of the volunteer's program on 17 September 2009. The outcome of this interview will determine when Ms. Poenisch can commence activity in the volunteer's program and lay out the requirements she must meet to become credentialed at WHMC. Certainly this delay has limited progression of the diabetes education program. On a positive note, we are prepared to fully operationalize ADA Recognized program as soon as we are able.

In addition to the aforementioned challenge, we have also identified three additional challenges that will likely impact the diabetes education program.

- Hemoglobin A1C values cannot be obtained at the time of the visit, so realistic plans and insulin adjustment cannot be made at the appointment and limits the quality of the diabetes education session. Use of point-of-care testing for A1C allows for timely decision-making regarding therapy changes, when indicated.
- Physicians have very limited availability to discuss processes, schedules, and patient care. However, with time, we anticipate that a system will be developed to more efficiently address these patient-related issues.
- Limited space is available to meet with patients and store supplies. We acknowledge that the issue of space is a global challenge at WHMC.

Despite these limitations, we are able to provide diabetes education to a limited number of pediatric diabetic patients treated at WHMC. Patients receiving diabetes education will continue to grow and return for multiple visits, which will allow us to provide a more robust and longitudinal assessment of the impact of the diabetes education program. We will measure attainment of patient-defined goals and patient outcomes at regular intervals using appropriate measurement techniques to evaluate the effectiveness of the educational program. In addition, we will determine opportunities for continuous quality improvement and document a systematic review of the programs' successes and outcome data. We anticipate that enhancement of the pediatric diabetes education program at WHMC will result in improved metabolic outcomes and diabetes-related quality of life for pediatric diabetic patients and reduced short and long-term costs for patients and payers.

2.2.4 WHMC Center of Excellence for Pediatric Diabetes: A Business Case Analysis

A Center of Excellence (COE) in pediatric diabetes is being recommended for implementation at WHMC. This recommendation is made to address the short supply of specialty resources in the military and to provide a viable way to attend to the increasing prevalence of diabetes in children and adolescents. Establishing and sustaining the COE will require investment by existing and future stakeholders, including the UPMC, the Air Force, and the Department of Defense. As such, a business case analysis (BCA) serves as a useful document to help vested parties make informed decisions regarding the development of a COE in pediatric diabetes at WHMC.

Existing Program Description

Pediatric diabetic patients from WHMC and BAMC are seen within the Pediatric Subspecialty Clinic at WHMC by two pediatric endocrinologists. Providers are supported, as needed, by social workers and a psychologist from Child and Adolescent Psychiatry. Additional support is received from the registered nurse and technician who are part of the subspecialty clinic and shared by all services that use the clinic. Attending physicians also travel to Ft. Hood two days a month (four days total) and one physician travels to Ft. Polk in Louisiana one day every other month.

Pediatric endocrinologists identify and treat medical issues for pediatric patients. They also provide diabetes education, address psychosocial issues, respond to telephone inquiries from caregivers (i.e., insulin regulation), and communicate with school nurses regarding management plans. Medical histories and physical exams are left to the primary care provider to handle due to time constraints placed on the pediatric endocrinologists. Pediatric endocrinologists also treat patients other than diabetic patients. Heavy patient loads and lack of support from a diabetes educator and dietitian limit the quality and quantity of diabetes care given to pediatric patients seen at WHMC.

An estimated 4 to 6 new diabetes cases are treated each year and approximately 15 pediatric patients with diabetes are seen each week (approximately 200 unique patients per year) by the pediatric endocrinologists at WHMC. While the new patient load is minimal, due to the high turnover rate and parental deployment in the military, patients and families often need to be reeducated or need to receive updated education on self-management of their condition. Endocrinologists recognize a significant need for diabetes counseling to help patients and families control hemoglobin A1C values and address emotional/mental blocks which serve as barriers to diabetes self-management and a system for monitoring the effectiveness of such counseling. Furthermore, findings from an assessment (Section 2.2.3) of pediatric diabetic patients treated at WHMC emphasize the critical need to provide patients and parents with on-going, evidence-based DSME.

Proposed Program Description

<u>"Best Practices"</u>
The pediatric diabetes clinic at Children's Hospital of Pittsburgh of UPMC (CHP) is considered a Center of Excellence in pediatric diabetes. It serves as a model for standards of care, which are recognized by ADA. Herein is a description of the patient population, staff mix, and DSME program.

Patient Population
The CHP diabetes clinic serves a population of approximately 2,500 children and adolescents aged 6 months to 21 years.

Staff
CHP has identified the following staffing mix as necessary to provide adequate diabetes care to the 2,500 youth seen at the clinic. It should be noted that the CHP diabetes clinic provides both inpatient and outpatient services. Significantly more new patients are treated at CHP than at WHMC, which requires greater attention from physicians, fellows, and nurse practitioners. Each diabetes educator is responsible for approximately 350 patients.

- 12 Attending Physicians

- 2-3 Fellows
- 2 Physician Assistants
- 4 Nurse Practitioners
- 7 Diabetes Educators (includes 1 coordinator)
- 2.5 Registered Dietitians (RD)
- 0.5 Social Worker
- Support Staff (Registers and Patient Information Coordinators)

Patient Visits

- Initial visit: All newly diagnosed patients are admitted to inpatient care for 3 to 5 days. During this inpatient visit, the patient and family will meet with an attendee, a diabetes educator for approximately 6 hours and an RD for approximately 3 hours.
- First outpatient visit. One month after discharge, the patient will meet with entire diabetes team, including the attendee, diabetes educator (~2 hours), and RD (~1 hour), and may attend a group diabetes education class.
- 2 month follow-up visit: Meet with the whole team, similar to the first follow-up visit.
- Every 3 months after: Typically meet with diabetes educator each visit and with the registered dietitian at least once a year. However, level of care or provider involvement is dependent on patient compliance.

Additional Services

- Call center: Diabetes educators are on call from Monday-Friday 7am-5:30 pm and Saturdays 7 am-noon to address patient and family needs, including providing guidance on insulin adjustments, blood glucose monitoring, and sick days. Attendees are on call for night calls. The heaviest call load occurs from 7-9 am, with approximately 50 calls being received each day during this time period. Three nurses handle the morning load; after 9am, 1 nurse mans the call line. The call center is ideally designed to serve newly diagnosed patients and families, who typically call every day for 2 weeks. The goal is to try to support patients and families to self-manage their diabetes, and to this end, nurses attempt to decrease call frequencies for each family to once a week, if possible, and then to faxing. If after 2 months families are still calling the phone line every day, at the 2 month visit a nurse and/or attendee tries to address the family's difficulty with their self-management plan. However, some families continue to use call line indefinitely.
- Diabetes Camp: A one week ADA camp occurs in the summer and is staffed by CHP medical professionals. The camp is designed for children and adolescents aged 8 – 16 years; approximately 130 youth attend each year. The camp's purpose is to foster relationships among youth with diabetes and provides a safe environment for youth with diabetes to participate in various activities.
- Group Education Sessions: Used in place of or to supplement one on one patient education. Group education sessions are typically offered twice a week for groups of 10 – 15 patients or patient-parent dyads. Sessions address diabetes self-care behaviors and are led by diabetes educators and/or RDs, depending on the topic.

DSME Program

A defining characteristic of a COE in pediatric diabetes care is fulfillment of ADA National Standards for DSME (20). ADA-approved DSME programs provide patients intense and ongoing DSME that addresses nutritional management; physical activity; monitoring; medication; preventing, detecting and treating acute complications; goal-setting and problem-solving; psychological adjustment; and treating chronic complications through risk reduction. DSME programs that comply with the ADA National Standards are

eligible to apply for ADA Education Recognition. Recognition identifies quality DSME services that meet the National Standards. In addition, recognized DSME programs meet criteria for Medicare and other third-party payer reimbursement.

CHP's DSME program, which participates in the ADA Recognition Program, addresses the full spectrum of diabetes, including diagnosis, regulation, treatment, and self-management education. DSME services available are in accordance with ADA requirements and described below.

- Curriculum: Reference curriculum is used as a written guide for instruction. Curriculum includes a detailed content outline, learning objectives, methods of delivery and a means of evaluating participant learning and addresses the ADA-required content areas for self-care behaviors.
- Assessment Plan: A comprehensive assessment is conducted with each patient. This assessment, which is ongoing, includes the child's and family's diabetes knowledge, self-management skills, diabetes and health-related behaviors, behavioral change potential and other relevant information, including medical history, diabetes history, and social history. The individualized assessment is used to develop a tailored education plan for each patient. Periodic reassessment between patient and instructor directs the selection of appropriate educational materials and interventions.
- Education Plan: The education plan includes patient identified behavioral objective(s) (with educator assistance as needed), how the patient will change the behavior(s), and how that change in behavior(s) will help to improve the patient's health or quality of life. After the educational intervention, the educator assesses and documents whether the patient meets the outlined objectives, and new objectives should be developed as appropriate. If the patient is unable to meet the outlined objective, his or her needs are reassessed and new achievable objectives are developed. The follow-up assessments and progress towards objectives are documented.
- Quality Improvement: CHP uses a continuous quality improvement process to evaluate the effectiveness of the education experience provided, and determine opportunities for improvement.
- Monitoring System: The CHP DSME documentation process and monitoring system is built into hospital's electronic charting system. CHP keeps record of information for general education, pre-insulin pump, insulin pump, basal bolus regimen, and diabetes management outcome data. Instructors record any barriers to learning (i.e, cognitive deficit, cultural barrier, emotional state, financial concerns), who was taught (i.e., patient, mother, father, grandparent, sibling), teaching method (i.e., oral instruction, demonstration, printed materials, audio, video), topics of education covered, educational resources utilized, and educational plans/goals. There is also a section to track what areas of education (i.e., pathophysiology of diabetes, properties of insulin, signs/symptoms of hyperglycemia) have been covered, if the areas need to be reviewed, and if any comments need to be noted. In addition, there is a place to note which instructional staff members conducted the education. Finally, to meet the requirements of quality improvement, a section exists to record information about diabetes management outcomes data. Using a 5-point Likert scale (never, seldom, half the time, usually, and always), instructors can record their assessment of patient adherence to behavior change as it relates to the ADA-required curriculum areas (i.e., nutrition, physical activity, medication, monitoring, prevention of complications, psychosocial adjustment, and goal setting).

At least 2 outcomes are be tracked as a measure of program success. One outcome is a patient defined behavioral goal and measure of goal attainment. The other outcome is metabolic, clinical, quality of life, or a process outcome with a measure of attainment. For ADA reporting, every month CHP pulls 20 charts and review 7 behaviors monitored for ADA Recognition, hemoglobin A1C values, and diabetes educator and RD recommendations. Data are entered into a standardized form and reviewed on a regular and ongoing basis.

A Description of how the COE will Solve Problems Associated with Existing Processes/Modes of Operation

The primary problem with the existing mode of operation is that attending physicians do not have sufficient time and resources to meet the demand of patient DSME needs. In addition, there is not a systematic method for monitoring patient compliance or addressing issues that impede or facilitate self care. Complementing existing services with a DSME program, administered primarily by a diabetes educator and supported by an RD and social worker or psychologist, and implementing a monitoring system would improve pediatric diabetes care provided at WHMC. Furthermore, developing a DSME program that complies with the ADA national standards would ensure that services meet third party reimbursement criteria.

A Description of how the COE will Function

We envision three ways in which the COE for pediatric diabetes could function. First, a DSME program could be added to the diabetes services currently provided as part of the Pediatric Subspecialty Clinic and collectively be considered the "Pediatric Diabetes COE." This option would minimally impact existing processes. Alternatively, the Pediatrics Diabetes COE could separate from the Pediatric Subspecialty Clinic and operate as an independent clinic. This option would require allocation of space and support staff and would have a greater impact on existing processes and infrastructure. A third option would be to merge the Pediatric Diabetes COE with the adult Diabetes COE. This option would centralize diabetes services provided to all patients at WHMC allowing for shared support staff and resources.

Cost-Benefit Analysis

<u>Analysis of cost and benefits based on the CHP model</u>
Data analysts at CHP developed a cost-benefit analysis for outpatient services provided at the CHP diabetes clinic. As shown in Table 7, the analysis is categorized by individual clinic session, lab work, group education sessions, and continuous glucose monitoring, that latter of which is reviewed at quarterly routine clinic visits. Each category is sub-divided into revenue and expense sections. Revenue-generating items are services (by quantity) that are charged for and reimbursable by third party payers. Reimbursement rates included in the analysis were obtained from the Tricare website; WHMC's specific contract with Tricare through Humana could vary. Expenses represent costs incurred for the services based on the provider/staff's salary and average time required to administer a particular service. Laboratory services are listed but charges are not included in the analysis due to the fact that they vary significantly between facilities depending upon equipment needs, economy of scale, and if labs are purchased from outside services. These and other assumptions are noted in the appendix.

Based on the CHP model, routine outpatient diabetic services net profit as summarized below (and detailed in Table 7).

Individual Clinic Session	$ 4
Group Education sessions	$446
Continuous Glucose Monitoring	$ 95

Assuming that WHMC follows a similar model for outpatient services, that reimbursement rates are comparable, and that the patient load is great enough to support provider/staff costs, WHMC can expect to generate revenue from the Pediatric Diabetes COE.

Table 7. Children's Hospital of Pittsburgh of UPMC's Diabetes Clinic Cost-Benefit Analysis

Individual Clinic Session	**Quantity**	**Minutes**	**Amount**
Revenue [5]			
99214 E&M, Established Patient, Detailed, Moderate Complexity [1]	1		$ 67
G0108 Diabetes O/P Self-mgmt training services, indiv [2]	1		17
97803 Medical Nutrition Therapy, reassessment, indiv [2]	2		39
36415 Venipuncture [3]	1		3
81002 Urinalysis, non-automated, w/o microscopy [3]	1		-
82044 Urine, microalbumin, semi-quantitative [3]	1		-
82947 Glucose; quantitative, blood [4]	1		-
83036 Hemoglobin; glycosylated (A1C) [4]	1		-
			$ 127
Expense [6]			
Physician		25	38
Diabetes Educator		30	18
Dietitian		30	14
Phlebotomist [4]		15	4
Medical Assistant (vitals & urine dipsticks) [3]		20	5
Medical Technologist (lab work) [4]		-	38
Patient Information Coordinator (registration & check out)		20	6
Social Worker [7]		-	-
			$ 123
Net P&L			**$ 4**
Yearly lab work (performed in conjunction w/ a quarterly visit)			
Revenue [5]			
82043 Urine, microalbumin, quantitative [4]	1		$ -
82465 Cholesterol [4]	1		-
84439 Thyroxine; total - free [4]	1		-
84443 Thyroid stimulating hormone [4]	1		-
			$ -
Expense			
Medical Technologist (lab work) [4]		-	**$ 113**
Net P&L			**$ (113)**
Group Sessions [8]			
Revenue [5]			
G0109 Diabetes O/P Self-mgmt training services, group [2]	40		$ 390
97804 Medical Nutrition Therapy, group [2]	20		214
			$ 604
Expense [6]			
Diabetes Educator		150	$ 88
Dietitian		90	41
Patient Information Coordinator (registration & check out)		100	29
			$ 158
Net P&L			**$ 446**

Continuous Glucose Monitoring [9]			
Revenue [5]			
95251 Ambulatory continuous gluc mon, up to 72 hrs, MD interp & report	1		$ 39
95250 Ambulatory continuous gluc mon, up to 72 hrs (technical fee)	1		113
			$ 152
Expense [6]			
Physician		20	30
Diabetes Educator		45	26
			$ 57
Net P&L			**$ 95**

Diabetes Clinic Assumptions & Notes

General Assumptions:

- Assume returning out patients. New patients are typically seen for in patient visits for approximately 3 days.
- CPT codes are based upon CHP history. Other codes, especially labs, can be ordered at times at physician's discretion, however, standard items only are listed.

(1) E&M code 99214 represents over 90% of return patients, which is used in this model; 8% receive 99215, comprehensive, high complexity. If needed, can also charge 99354 & 99355 for prolonged services.

(2) Quantity based upon CHP average median in March 09.

(3) Urine dipstick tests performed by clinic medical assistant in lab.

(4) Blood drawn by phlebotomy clinic and tests performed by lab medical technologists. Lab work based upon internal cost charged to CHP by parent. Lab costs could significantly vary for WHMC depending upon equipment needs, economy of scale, and, if necessary, outside lab purchased services:

$ 8.00	82947 Glucose
30.00	83036 Hemoglobin
$38.00	
$22.00	82043 Urine, microalbumin, quantitative*
15.00	82465 Cholesterol
45.00	84439 Thyroxine; total – free
31.00	84443 Thyroid stimulating hormone
$113.00	

* Overnight test occurs less frequently as it is not administered on the newly diagnosed and not until at least age 5. Also, some physicians do not request for the first 2 years of diagnosis. Listed in model but total volume is roughly only 30% of other yearly tests from sample population.

(5) Reimbursement rates obtained from www.mytricare.com. Links lead to CMAC rates at www.tricare.mil/CMAC/ProcedurePricing/CMACDetails.aspx. This is the generic maximum rate. WHMC's specific contract could vary. Assumption is that E&M reimbursed as Category 1 –Facility Physician and remainder performed by Category 3 – Facility Non-Physician. Changes in category can alter reimbursement.

(6) Staff time based upon CHP clinic experience. Rates based upon CHP mid point salary for position + 24% benefits.

(7) CHP social worker is involved as necessary. Highly variable and not built into model.

(8) A charge is dropped for each patient in attendance of a group session. CHP typically holds 2 classes per week with 10-15 families in attendance. WHMC P&L will depend upon the class size. Class of 10 shown for illustration purposes. Each patient would receive educator quantity of 4 at $9.76 each and nutritionist quantity of 2 at $10.68 each. Assuming 30 minutes paperwork and coding for each instructor and 10 minutes registration per patient.

(9) Continuous Glucose Monitoring is reviewed at normal 3 month sessions. Educator connects equipment and reviews its use. Family mails in after data collected. Educator downloads data and produces report, which the physician then reads. Time listed is an estimate of the entire cycle.

Other Costs

In terms of DSME services, additional costs will result from time spent by the diabetes educator responding to patient telephone inquiries (i.e., insulin management), developing and communicating management plans to school nurses, and developing educational materials and interventions. In addition, depending on patient and educator needs, educational and reference materials and resources will need to be purchased. The following educational materials are purchased by CHP and provided to patients/families with diabetes.

- Every patient gets the book entitled, "Raising a child with diabetes" ($16.95) as well as the American Diabetes Association booklet, "Choose Your Foods: Exchange Lists for Diabetes" ($2.25).
- Depending on the age of the patient, the family will get one of the following additional publications:
    - Diabetes Care for babies, toddlers and preschoolers - $15.95
    - Its time to learn about Diabetes for school age (6-12 years) - $14.95
    - Its time to learn about Diabetes for school age DVD (6-12 years) - $10.95
    - In control for teens - $10.95
- CCS Medical provides a bag that has 2 meters, 50 test strips, 100 lancets (no charge). A "Getting Started" kit from BD provides some syringes (no charge). We provide 1 sharp box ($4.48).
- Other 1-page educational materials are copied by the department and given at diagnosis as well as at follow-up visits.

Vendors often provide educational materials and diabetes-related supplies at no charge, so some of the items listed may be supplemented at no cost.

Other Benefits

The ADA recommends intense and ongoing DSME as an effective means for patients to properly manage their diabetes thereby improving their diabetes-related quality of life, reducing their diabetes-related hospitalizations and emergency room visits, and decreasing incidence and progression of acute and chronic complications (17-19). Positive outcomes of DSME for the patient translate into financial benefit for the provider and payer. Hospitalization and emergency room care rates and costs are significantly lower in diabetic youth with controlled diabetes (21).

WHMC may realize additional financial benefits by establishing a Pediatric Diabetes COE. Patients presently seeking treatment for diabetes from providers in the network (or outside of the network), may opt for services from the COE. Similarly, primary care providers in the San Antonio catchment area may increase the referrals they make to WHMC. These changes would enable WHMC to keep funds in-house rather than allocating them to the network.

Assumptions and Risk Assessment

Key Assumptions

- Development of a Pediatric Diabetes COE is a priority of the Air Force and Army (given BRAC realignment)
- Existing providers and staff involved with providing pediatric diabetes services support creation of a Pediatric Diabetes COE
- Air Force pediatric endocrinologists (n=2) will continue to provide medical supervision and assessment

- WHMC will provide infrastructure and financial support required to maintain the Pediatric Diabetes COE.
- Tricare and other third-party payers will reimburse for diabetes services, including DSME.
- Cost and benefits related to diabetes services provided at WHMC are similar to those provided in the CHP model analysis.
- Development of a Pediatric Diabetes COE will lead to improved metabolic control, reduced acute and chronic complications, decreased rates of hospitalization and emergency room visits, and an overall reduction in diabetes-related costs.

Risks

- Development of a Pediatric Diabetes COE is not a priority for the Air Force and Army and/or infrastructure and/or financial support are not provided. This will most immediately impact the DSME program since the diabetes educator and related supplies are presently funded by grant dollars.
- Existing providers and staff involved with providing pediatric diabetes services will not support and/or continue to provide their services, which will jeopardize the quality and efficiency of diabetes care.
- Development of a Pediatric Diabetes COE will result in an increased demand for services, which may lead to need for additional providers and staff.
- Tricare and/or other third-party payers will not reimburse for some or all of diabetes services. This is unlikely given the Medicare and other third-party payers recognize programs that meet ADA requirements. However, Lt. Col. Nina Watson, WHMC, and Janis McWilliams, UPMC, previously explored opportunities to bill for DSME services provided at WHMC. In their investigation, they learned that Tricare (and other government agencies like the Veteran's Administration) do not have the capabilities in their respective billing systems to charge against a HCPCS G code for DSME provided at WHMC. Inability to charge against G codes prohibits charging for the service. Until these issues are resolved, billing processes cannot occur without the related coding.

  On 31 August 2009, the DoD published a Federal Register Notice that clarified Tricare coverage for diabetic education. According to the Notice, Tricare previously classified diabetes self-management training as a counseling service that was not considered medically necessary. Services that are deemed unnecessary are not covered by Tricare. However, while developing a policy on diabetes self-management therapy, Tricare has determined that diabetes educational services are medically necessary and has subsequently decided to conform to Medicare's DSME policy. Our team, headed by Linda Siminerio, UPMC, is preparing to submit comments to the Notice to further clarify the meaning of the policy change.

Change Management Plan

UPMC and the Air Force and with participation from SGR and DoD will lead implementation of the Pediatric Diabetes COE. This project will be implemented in two phases. Phase 1 is the testing phase. During this phase, salaries and supplies for DSME will be fully funded by grant dollars. This time period, which has already commenced and is secured through 31 December 2010, offers the opportunity to adequately identify actual revenue and expenses for the program, establish payer reimbursement, and make changes to optimize revenue. It also offers a period of time to validate the programmatic efforts adding DSME services, including evaluating improvement in clinical and behavioral outcomes.

We have already developed and implemented an ADA Recognized DSME program for pediatric diabetes at WHMC that meets the ADA national standards (Table 4). As highlighted in section 2.2.3., patients and parents were highly satisfied with the diabetes education they received as part of the recently established DSME program.

The second phase is the full fielding phase. Initiation of this period will commence upon withdrawal of grant support and be defined by sustained support by the military and their government partners. Prior to the second phase, we recommend a critical review of how diabetes care has changed with the addition of DSME services to complement the existing program.

2.3 FEASIBILITY STUDIES

This section provides a description of two Focus Area 1 feasibilities studies conducted at CHP as part of the WMWC's mission to advance health care delivery of pediatric obesity services and explore effective treatment modalities.

Goal 7: Academic detailing of community-based pediatricians
Goal 8: Physical activity in overweight youth: implications for reversing risk factors of type 2 diabetes

2.3.1 Academic Detailing of Community-Based Pediatricians

Effective and safe pediatric obesity prevention and treatment programs are not widely available. Specialized centers offer effective intensive counseling programs for obese children that promote behavior modification. Unfortunately, such programs can at best accommodate a tiny fraction of the nation's obese children. The widespread use of medications to treat childhood obesity is likely many years away. Significant environmental and societal change holds the promise of reversing the problem. This will likely require change in public policy that affects, for example, how certain foods are marketed to and packaged for children. Environmental changes take a long time to bring about and even longer to have a substantial impact on children's health. Today, settings in which identification, prevention and treatment of pediatric obesity is practical and rational include schools, where children spend much of their time, and primary care practices, through which they receive much of their care.

The American Academy of Pediatrics recommends that physicians recognize overweight and obesity among their pediatric patients, provide counseling and other treatments to prevent excessive weight gain among all children, and manage obesity-related diseases (22). Unfortunately, primary care physicians consistently report a lack of self-efficacy in identifying, preventing and treating obesity and its associated co-morbidities. According to the U.S. Preventive Services Task Force (USPSTF), this is related to the lack of obesity research in primary care settings. No practical tools designed for providing obesity-related counseling and managing obesity-related illnesses have yet been developed and systematically evaluated (23).

Objective

The purpose of this study was to develop and implement a system of physician education about childhood obesity through academic detailing, and to measure the impact of the program upon the

frequency and quality of obesity-related counseling, and upon weight of overweight and obese children who receive counseling from trained physicians.

Methods

Institutional Review Board approval was obtained from the University of Pittsburgh.

Recruitment

Practices and physicians interested in participating in the study were recruited by Dr. Goutham Rao in collaboration with two physician liaisons from CHP. Potential participating physicians were provided with a brief, written description of the study and provided informed consent. Physicians practicing in underserved, rural areas of western Pennsylvania were targeted.

Academic Detailing

Academic detailing is a form of educational outreach in which a trained individual makes personal visits to physicians to deliver an educational message, much the same way as a pharmaceutical representative provides education about products. For the purposes of this study, Dr. Rao trained a clinical practice advisor (CPA) to deliver a structured educational program to physicians at their convenience. The program consisted of three visits; content of each visit is described below.

Visit One: The CPA provided an overview of the study and reviewed the "5As paradigm" for counseling children and families for prevention and treatment of obesity (see below). The CPA also distributed useful materials such as patient education handouts, prescription pads for providing patients with goals for behavior change, and flow sheets for tracking patients' progress and laboratory values (Table 8; flow sheets were based on recommendations of the American Medical Association's Expert Committee on the Assessment, Prevention and Treatment of Child and Adolescent Overweight and Obesity (24).

Visit Two: The CPA introduced participating physicians to an online course developed by Dr. Rao entitled *Childhood Obesity: Practical Primary Care Approaches* in which the epidemiology and consequences of childhood obesity, the 5As paradigm, and billing and coding recommendations for childhood obesity were reviewed. The CPA also solicited feedback about the course and any other materials, as well as addressed any concerns or problems that arose.

Visit Three: The CPA made an optional third visit to physicians to address any other concerns and interviews participating physicians to answer the question, "What else would you like to provide better care for childhood obesity?"

5As Paradigm

The 5As paradigm was originally developed by the National Cancer Institute (NCI) for smoking cessation counseling by physicians, and has been adopted by Dr. Rao for childhood obesity (25, 26). Each component is described below:

- Ask/Assess: Physician asks patient about motivation to achieve a healthier weight and identifies common behaviors contributing to obesity (e.g. sweetened beverage consumption).
- Advise: Physician advises patient about behaviors contributing to obesity. The "advice" provided by physicians should be based upon the latest evidence and delivered in as objective a way as possible: e.g. "Soft drinks and other sweetened beverages are a leading cause of weight

problems. It is recommended that your child limit his consumption of these products in order to achieve a healthier weight."

- Agree: Physician, patient, and patient's family negotiate an agreement on changing specific behaviors within an agreed-upon time period.
- Assist: Physician provides "tips" and information for patients on how to reach agreed-upon goals.
- Arrange: Physician arranges follow-up to re-assess weight and progress in meeting goals.

Baseline and Follow-up Assessments

Data about the counseling rate and quality of counseling provided by each physician were collected over a two-week period prior to the first academic detailing visits. The CPA provided each physician's practice with a large number of post-encounter forms (Table 9). The post-encounter form simply asks parents of patients whether the physician raised the issue of weight and if so, which specific topics were discussed. These topics pertain to known contributors of childhood obesity. The CPA informed office staff and nurses in each physician's practice about the purpose of the form and asked that a form be given to all patients for completion immediately after their encounter.

Post-encounter forms were collected approximately 1 – 2 months after the second academic detailing visit, after which all physicians had received the complete educational program, and approximately 1 – 2 months after the third academic detailing visit, to determine if any improvements in counseling frequency and quality were sustained.

Eight to 11 months after the start of study the last 50 – 75 established patients of each participating physicians were asked to provide informed consent for chart reviews. Charts were reviewed to determine 1) if the patients had received obesity-related counseling in the past year, and if so, 2) if they were overweight at the time of receiving obesity-related counseling, and 3) if their weight (determined by age and sex adjusted BMI percentile) had improved. Consent was obtained without knowledge of whether patients had received counseling and without knowledge of patients' weight status. Only a small number of charts per physician, therefore, were expected to contribute data to provide a crude clinical measure of the impact of counseling.

Table 8. Flow Sheet

Patient Name: Last_____; First _____
DOB: __/__/__
Medical record no: _____

Date	**__/__/__**		**__/__/__**		**__/__/__**		**__/__/__**	
Height								
Weight								
BMI (kg/m^2)								
BMI Percentile								
Blood Pressure (mm/Hg)								
Blood Pressure Percentile								
Reported sweet beverages per day + goal		**Goal**		**Goal**		**Goal**		**Goal**
Fast food freq./wk +goal								

Family meals freq./wk + goal								
Physical activity (days>=30mins)/wk + goal								
Reported media time in hours/day + goal								
Additional behavior #1								
Additional behavior #2								

Lipid profile (mg/dL)	Tot. Cholesterol				
	LDL				
	HDL				
	Triglycerides				
Fasting glucose (mg/dL)					
AST (U/l)					
ALT (U/l)					
BUN (mg/dL)					
Creatinine (mg/dL)					

Lab Recommendations for One-Time Screening

If age and sex-adjusted BMI Percentile is:

a. 85 – 94 without risk factors: Fasting lipid profile only
b. 85-94 and age ≥ 10 with risk factors: Fasting lipid profile, ALT, AST, & fasting glucose. (*ALT & ALT may be repeated every 2 years)
c. ≥95 and age ≥ 10 Years with/without risk factors: All in (b) plus BUN and creatinine

Weight Loss Targets**

	BMI 85-94 percentile	**BMI ≥ 95th percentile**	**BMI (≥21 or 22) percentile (Rare, very high)**
Age 2-5 years	Weight maintenance until BMI < 85%ile or slowing of wt. gain as indicated by downward deflection in BMI curve.	Weight maintenance until BMI < 85%ile; if weight loss occurs with a healthy & adequate caloric diet it should not exceed 1 lb/month. **	Gradual weight loss, not to exceed 1 lb/mo.**
Age 6-11 years	Weight maintenance until BMI < 85%ile or slowing of wt. gain as indicated by downward deflection in BMI curve.	Weight maintenance until BMI < 85th percentile or gradual weight loss of approximately 1 lb/month. ***	Weight loss not to exceed an average of 2 lb/week. ***
Age 12-18 years	Weight maintenance until BMI < 85%ile or slowing of wt. gain as indicated by downward deflection in BMI curve.	Weight loss until BMI < 85%ile – no more than 2 lbs/week. ***	Weight loss not to exceed an average of 2 lbs/week. ***

***** Frequency of follow-up can vary according to patient needs/wishes and capacity of practice and physicians, but should take place approximately every 2 – 4 months.

****** Grey M, et al. *Expert Committee Recommendations for the Prevention, Assessment, & Management of Child and Adolescent Overweight & Obesity.* American Medical Association, June 6, 2007.

******* If greater loss occurs, monitor for causes of excessive weight loss.

Table 9. Post-Encounter Form

INSTRUCTIONS: Please place a check mark next to the answer to each question.

1. During your doctor's visit today, did your doctor mention or discuss your child's weight?
   Yes ___ No ___

2. If your doctor did discuss your child's weight, which of the following specific topics did he or she discuss with you or your child? (Place a check mark next to each topic discussed.)

   ___ My child's weight compared to other children the same age.
   ___ Avoiding soft drinks and other sweet drinks.
   ___ Reducing the amount of fast food (e.g. hamburgers, fries, chicken nuggets) my child eats.
   ___ Increasing physical activity such as walking or organized sports such as basketball.
   ___ Reducing the amount of television my child watches, and the amount of time my child spends playing video games or using a computer.
   ___ Encouraging the entire family to have healthy, family meals together as often as possible.

   Other topics discussed (Please list.)

   1. _____
   2. _____
   3. _____

Outcomes and Analysis

The proposed research was designed to answer the following questions related to outcomes based on the measurements described above:

1. Does the proportion of encounters in which obesity-related counseling is delivered change for each physician enrolled in the study?
2. Does the quality (as measured by the mean number of obesity-related topics discussed) of obesity-related counseling change for each physician enrolled in the study? *(Comparison of the mean number of elements of obesity-related counseling discussed by each physician (as determined by analysis of post-encounter forms) during the three different collection points.)*
3. Does the BMI percentile (age and sex adjusted BMI) of overweight and obese children of each physician change? *(Calculation of mean change in BMI percentile per month (i.e. rate of BMI percentile change) for the patients of each physician participating in the study who receive obesity-related counseling.)*

Statistical Analysis

All statistical analyses were completed using SPSS Version 13.0 (SPSS, Chicago, IL). Parametric tests or their non-parametric equivalents were used to compare changes in counseling rates and the mean number of elements of obesity-related counseling discussed by each physician at the different time points. Charts were reviewed to generate a mean BMI percentile change/month for each physician's overweight and obese patients.

Results

Recruitment and Completion of Visits

Twenty-three primary care pediatricians representing seven practices were successfully recruited. For data purposes, one father and son practice (in which both physicians saw patients interchangeably) was treated as one physician. This was because patients in this practice were not formally assigned to either physician and saw them interchangeably. The total number of physicians for the purposes of analysis is therefore 22. All practices were located in rural or semi-rural parts of western Pennsylvania. The sample consisted of 11 male physicians and 12 female physicians. First academic detailing visits were completed by early fall 2007. Second visits were completed by early February 2008. Third visits were requested and provided to all practices and completed in spring 2008.

Baseline Counseling Rates

A total of 1977 post-encounter forms were collected at baseline from practices. All twenty-three physicians were represented. The number of post-encounter forms ranged from 35 to 161 per physician. Table 10 shows the baseline counseling rates (i.e. proportion of encounters in which patients reported that a child's weight was discussed) for each physician. Weight status was brought up in a mean of 51% of encounters with a range of 35 to 74% at baseline.

Table 10: Baseline Proportions of Encounters in which Weight was Discussed

Physician ID	Proportion of Encounters in which Weight was Discussed	N
1	.46	59
2	.42	52
3	.60	35
4	.68	102
5	.61	70
6	.46	67
7	.74	103
8	.37	99
9	.60	73
10	.54	155
11	.58	84
12	.35	63
13	.49	73
14	.62	47
15	.45	288
16	.36	80
17	.70	84
18	.40	130
19	.59	58
20	.42	125
21	.51	72
22	.50	58
Total Mean	.51	1977

Counseling Rates after Second Academic Detailing Visit

1118 post-encounter forms were collected 1 – 2 months after the second academic detailing visit. All physicians were represented. However, as shown in Table 11, the number of forms collected from some physicians was very low. There was no significant difference overall between baseline and first follow-up counseling rates. Among individual physicians, the majority showed no significant change in how often they raised the issue of a child's weight in the encounters. One physician (3) had a significant improvement, but five others actually had a significant decrease in rates of counseling.

Table 11: First Follow-Up Proportions of Encounters in Which Weight was Discussed by Physicians

Physician ID	Proportion of Encounters in which Weight was Discussed	N	Difference from Baseline
1	.63	63	NS
2	.42	48	NS
3	1.00	9	0.4 (p =0.02)
4	.61	89	NS
5	.54	79	NS
6	.60	65	NS
7	.48	69	-0.26 (p < 0.01)
8	.26	57	NS
9	.37	51	-0.23 (p =0.01)
10	.65	31	NS
11	.35	31	-0.23 (p = 0.03)
12	.51	73	NS
13	.51	74	NS
14	.31	13	NS
15	.31	64	-0.14 (p=0.04)
16	.32	38	NS
17	.40	15	-0.32 (p=0.02)
18	.37	35	NS
19	.55	42	NS
20	.40	50	NS
21	.58	67	NS
22	.51	55	NS
Total mean	.49	1118	NS

Counseling Rates after Third Academic Detailing Visit and Numbers of Topics Discussed

Only 401 post-encounter surveys were collected after third academic detailing visits (Table 12). Only 12 of the original physicians were represented. Four physicians demonstrated statistically significant improvements in counseling rates, though there was no improvement in overall counseling rates in the entire sample of physicians between the second and third survey collections.

Table 12: Second Follow-Up Proportions of Encounters When Weight was Discussed by Physicians

Physician ID	Proportion of Encounters in which Weight was Discussed	N	Difference from First Follow-Up
2	0.60	25	NS
7	0.60	67	NS
8	0.40	47	NS
11	0.75	8	0.40 (p = 0.04)
13	0.33	30	NS
14	0.37	30	NS
15	0.40	92	NS
16	0.78	9	0.46(p=0.01)
17	0.55	22	NS
18	0.89	18	0.52(p = <0.01)
19	0.90	21	0.45 (p = <0.01)
20	0.50	32	NS
Total mean	0.52	401	NS

Number of Topics Discussed by Physicians

A mean of 1.38 topics (e.g., soft drinks, television, fast food --- See Table 9) were discussed at baseline in encounters in which the issue of weight was raised (range 0 to 7.00 with SD of 1.63). There was no statistically significant change in the mean number of topics discussed with the second or third survey collections (mean of 1.31 topics at each follow-up collection period). Only the number of topics was collected and analyzed from post-encounter forms as a measure of the depth or quality of obesity-related counseling. It is not known the extent to which particular topics were discussed in each encounter.

Chart Review Data

Though consent for chart reviews was requested from 50 – 75 patients per physician, a disappointing total number of just 31 patients provided consent, making trends per physician impossible to determine. In only four cases was BMI percentile documented more than once, allowing patients' progress to be determined. The small number of charts reviewed, however, did provide a glimpse into documentation of weight and related issues by participating physicians. Overall results are summarized in Table 13.

Table 13: Summary of Chart Reviews

	BMI documented in past year	BMI percentile documented in past year	Obesity-related counseling documented in past year	BMI percentile documented more than once in past year
Absolute Number	19	18	12	4
% of total (31 charts)	61%	58%	39%	13%

Among the four patients for whom BMI percentile was documented more than once, two had no change in BMI percentile. One patient had a substantial increase in BMI percentile (25 to 85) over an eleven month period. The other had a substantial decrease in BMI percentile (85 to 75) over a twelve month period. It is unclear how these substantial changes took place. In any case, it is impossible to draw conclusions based on such a small sample of four patients.

Overall results showed insignificant changes in rates and quality of counseling through the duration of the study. In some cases, the rate of counseling actually decreased among physicians. There are several possible explanations for the disappointing results. First, though invitations to participate in the study were extended to all practicing pediatricians in a broad region, it is of course, inevitable, that only those with the greatest interest in pediatric obesity would enroll. These physicians may already have had high baseline rates of obesity-related counseling which would make further improvement difficult to promote. Indeed, the baseline counseling rate of 51% (for all types of encounters) indicates that addressing weight is a major part of the practice of the participating physicians. Decrease in counseling rates among some physicians is harder to explain. It is possible that the early enthusiasm of some physicians for obesity-related counseling waned with time.

Chart reviews indicated that BMI and or BMI percentile is documented in the majority of charts at least once a year and that 39% of charts include some documentation of obesity-related counseling. This is lower than the average rates of counseling calculated from post-encounter forms. As is common in many patient encounters, physicians may provide more service than they actually document in charts.

The net impact of the study is underestimated if only statistical improvements in counseling rates, quality of counseling, and significant changes in BMI percentile are taken into account. Through the study, participating physicians had the opportunity to improve their skills in the prevention and management of pediatric obesity through academic detailing and completion of the online course. They were also given tools (e.g. prescription pads with lists of goals) with which to enhance their counseling. The relationship between the Weight Management and Wellness Center and community-based physicians in rural areas of western Pennsylvania has flourished as a result of this study. Collaboration between the Center and these physicians led to the development of a useful flowchart tool. Finally, though it is difficult to measure, the awareness of the problem of childhood obesity the physicians promoted in their communities by actively participating in the study is unquestionably valuable to children and families.

The feasibility of this study was likely impacted by the fact that third parties were not providing reimbursement for obesity-related counseling in the region when the study was conducted. Since then, insurance companies, such as Highmark, have implemented or have considered implementing policies for obesity-related counseling. The present study may have faired better in such a climate. Furthermore, policy changes underscore the importance of developing obesity counseling procedures like the ones created for this study.

2.3.2 Physical Activity in Overweight Youth: Implications for Reversing Risk Factors of Type 2 Diabetes

Evidence suggests that the epidemic increase in childhood obesity has occurred parallel with a decline in physical activity levels in youth (27). Given that childhood obesity tracks well into adulthood obesity (28, 29) and that physically active youth more likely to remain physically active into adulthood (30),

adoption of a physically active lifestyle should be implemented early in life. At present, little is known about the utility of exercise alone as a strategy for the treatment of childhood obesity and related health risks. Thus, we proposed a randomized controlled trial to examine the independent effects of regular physical activity on total and abdominal adiposity, ectopic fat deposition in the liver and skeletal muscle, and risk factors for type 2 diabetes and cardiovascular disease in overweight boys.

Objectives

The objective of this study was to assess the feasibility of examining the independent effect of regular physical activity (e.g., without calorie restriction) on the risk factors leading to type 2 diabetes, most importantly insulin resistance in childhood obesity. Insulin resistance is strongly associated with abdominal fat, non-alcoholic fatty liver, ectopic deposition of fat in the skeletal muscle, metabolic and endothelial dysfunction in sedentary overweight youth who are at increased health risk.

The specific aims of this study were:
1) To investigate whether sedentary overweight youth gain health benefits and reverse the risk for type 2 diabetes and cardiovascular disease after increasing physical activity alone, and
2) To investigate the potential underlying mechanisms by which different exercise modalities (aerobic vs. resistance) influence total and abdominal obesity, and related co-morbid conditions (insulin resistance and cardiovascular disease).

Methods

This study was approved by the University of Pittsburgh IRB.

Laboratory Facilities, Personnel, and Equipment
The principal investigator (PI) of the study secured laboratory space for the exercise physiology lab at CHP by assessing available spaces and what would accommodate her research needs. Specifically, she needed a space that would accommodate exercise equipment and a metabolic cart and would be accessible to study participants. The PI, an exercise physiologist, also determined that she would need a research coordinator, nutrition educator/dietitian, and one to two trainers to run the study. The PI trained the staff, according to their respective roles, to conduct the research study. The PI also determined that she would need a metabolic cart, 2 treadmills, 1 elliptical and 2 resistance trainers to accommodate participant needs. In addition, to accommodate participant needs, the study subjects were given option to exercise with our trainers at the downtown Pittsburgh YMCA.

Subject Population
Overweight boys (BMI $\geq 95^{th}$ percentile) were recruited for the study. Inclusion criteria included that the subjects be 12-18 years of age, abdominally obese (age-, sex-, and ethnicity-specific waist circumference $\geq 90^{th}$ percentiles), non-smokers, non-diabetic, sedentary (no participation in any regular physical activity for past 6 months), and on no medications. The study protocol received IRB approval from the University of Pittsburgh. Participants were recruited from the WMWC, as well as via flyers posted in the city public transportation, University hospitals and facilities, local schools, and posters placed on the University of Pittsburgh campus. Parents who responded to these advertisements on behalf of their children were contacted by the research coordinator by telephone for the initial screening and were given the description of the research study.

For all subjects, screening was performed during a screening outpatient visit at the PCTRC at CHP, prior to enrollment in order to ensure the health condition of the subject. At that visit, potential participants and their parents met with our study coordinator and were fully informed about the nature of the research, risks and potential benefits of study participation, and rights as research subjects. After the consent form was signed, a complete medical history and physical examination was performed by a certified nurse practitioner similar to a routine doctor's appointment. During the examination, a detailed medical history and a physical examination including pubertal development was assessed according to the criteria of Tanner (31). Race was defined based on self-identity with no admixture for three generations (32).

Baseline and Follow-up Measurements

All measurements listed below were performed before and after the treatments. For 3 days prior to overnight stay at the PCTRC, all subjects were asked to follow a weight-maintaining diet containing at least 200-250 grams of carbohydrate/day and 1.5 kg/kg/day of protein, and refrain from the physical activity at least 48 hours prior to the baseline and follow-up measurements. Details of experimental methods are described below.

Oral Glucose Tolerance Test: To ensure normal glucose tolerance, a 2 hour, 75g oral glucose tolerance test was performed in the morning after an 8-10 hour overnight fast. Blood samples were drawn from the antecubital vein at -15, 0, 30, 60, 90, and 120 min to measure plasma glucose and insulin levels. Areas under the glucose and insulin curves was determined by a trapezoid model (33).

Anthropometric Measurement: Waist circumference was obtained at the level of the last rib and thigh circumference was measured on the right leg at the midpoint between the inguinal crease and superior edge of the patella.

Basal Substrate Turnover: This test was conducted to determine the amount and type (i.e., carbohydrate or lipids) of energy (i.e., calories) used by the body at rest. On the night before the measurement of insulin sensitivity, subjects were admitted to the PCTRC in the afternoon and stayed overnight. A standard dinner was provided (~50% carbohydrate, ~30% fat and ~20% protein) and subjects fasted until the completion of the clamp measurement on the following day. After the overnight fast, basal postabsorptive glucose and lipid turnover was evaluated using primed-continuous intravenous infusion of [6,6-$^{2}H_{2}$]glucose and [d-5]glycerol (34). Substrate oxidation was measured by continuous indirect calorimetry using the DeltaTrac metabolic monitor (Sensormedics, Anaheim, CA) for 30 minutes in the fasted state, prior to beginning the hyperinsulinemic-euglycemic clamp measurement.

Hyperinsulinemic-euglycemic Clamp: This clamp was used to measure insulin sensitivity. Following the baseline isotopic infusion period, a 3 hour hyperinsulinemic-euglycemic clamp was performed to evaluate *in vivo* insulin stimulated glucose disposal, oxidative and non-oxidative disposal, and insulin action in suppressing lipolysis and free fatty acid oxidation (34). Insulin was infused at 80 mU/m^{2}/min and plasma glucose was clamped at 100 mg/dl with a variable infusion rate of dextrose (20%) in water. The glucose levels were determined every 5 minutes for determination of euglycemia. During the last 30 minutes of the insulin infusion, indirect calorimetry using the DeltaTrac metabolic monitor (Sensormedics, Anaheim, CA) was employed to estimate glucose oxidation. Post-exercise training clamp measurements was performed at least 48 hours post-exercise after the last exercise session to control for the well-established effects of acute exercise on glucose uptake (35).

2-hour Hyperglycemic clamp: This clamp was used to measure of insulin sensitivity. During one of the two PCTRC admissions, and as stated above at random order, a two-hour hyperglycemic clamp was performed to measure first- and second-phase insulin and C-peptide levels. Arterialized plasma glucose was elevated to ~ 225 mg/dl with a bolus infusion of dextrose over 2 min. Plasma glucose was maintained at that level with a variable rate infusion of 20% dextrose for 2 hours as reported by us previously (36, 37).

Magnetic Resonance Imaging (MRI, 1.5 Tesla, T1-weighted**):** MRI was used to measure whole body and regional skeletal muscle and adipose tissue mass. Approximately 41 equidistance MRI images were obtained using the General Electric 1.5 Tesla magnet (Milwaukee, WI) using standard protocol (38). The total time required to acquire all of the MRI data for each subject was ~25 minutes. Once acquired, the MRI data was transferred to a personal computer for analysis using commercially available software (Slice-O-Matic, Tomovision, Montreal) as described previously (38).

Doppler Ultrasonography: Aortic pulse wave velocity (aPWV) was measured in the right carotid and femoral arteries after ~30 minutes of supine rest using Doppler ultrasound as reported previously (39). Briefly, pulse-wave velocity in the aorta was measured using 2 transducers: one to detect the pulse wave as it reaches the carotid artery and another to detect the pulse wave as it reaches the femoral artery. The time required for the pulse wave to travel from one probe to the other, combined with the distance between the two probes, allows for the determination of pulse wave velocity. Also, blood pressure cuffs were applied to both arms and ankles for blood pressure readings and additional blood flow data. Self adhesive patches with a small round microphone-like device were applied to the subject's chest to monitor heartbeat. The total time required for this measurement was ~30 minutes.

Cardiorespiratory Fitness: Peak oxygen uptake (VO_{2peak}) was determined using a graded maximal treadmill test that used a constant walking speed with the use of standard open-circuit spirometry techniques (SensorMedics, Yorba Linda, CA). For the initial 2 minutes, the grade was set at 0%, after which it was increased to 2% for the 3rd minute and by 1% every minute thereafter. The test was performed in the exercise physiology laboratory at CHP. VO_{2peak} was attained when at least 2 of the following 3 criteria were achieved: no increase in VO_2 despite further increases in treadmill grade, a heart rate $\geq$ age predicted maximum (220-age), and/or a respiratory exchange ratio in excess of 1.0 (40).

Exercise and Diet Regimen:

During a 3-month treatment period, exercise and diet regimens were rigorously monitored by exercise physiologists and the study dietitian. Subjects participated in 1 of 3 groups during the study: an aerobic training group (n=6), a resistance training group (n=6) and a control group (non-treatment group; n=2).

Aerobic training group: Subjects in the aerobic training group participated in a 3-month supervised aerobic exercise program, 3 times per week (~ 60 minutes/session), using treadmills, elliptical machines, or stationary bikes. Aerobic exercise programs were individually prescribed and progressive in duration and intensity such that for the first 1-2 weeks, subjects exercised for ~ 40 min at ~ 50% of VO_{2peak} and increased up to ~ 60 min at 60-75% of VO_{2peak} (brisk walking or light jogging) thereafter. Subjects wore a heart rate monitor (Polar Oy, Kempele, Finland) during the exercise sessions to achieve the target heart rate and estimate energy expenditure. The heart rate range (60-75% of VO_{2peak}) was determined during the baseline maximal oxygen uptake test and will be prescribed for each subject. The relationship between the heart rate and VO_2 was re-evaluated during the subsequent maximal treadmill tests. Each exercise session was by appointment and supervised under the directorship of the PI who has performed similar interventions in the past (41, 42).

Resistance training group: Subjects in the resistance training group participated in a 3-month supervised progressive resistance program that includes a series of 10 whole body exercises, three times per week (~ 60 minutes/session). Each training session included leg press, leg extension, leg flexion, chest press, latissimus pull down, seated row, bicep curl and triceps extension using stack weight equipment. Single set of push-ups and sit-ups were also performed. For the first ~ 4 weeks, proper lifting techniques was emphasized by the trainers and subjects performed 1-2 sets of 8-12 repetitions with ~ 60% of baseline 1 RM. During weeks 4-12, subjects performed 3 sets of 8-12 repetitions with 70%-100 % of baseline 1 RM. All exercise training session included 5 minutes of warm-up and 5 minutes of cool-down on a treadmill. Each exercise session was by appointment and supervised by undergraduate and graduate physical education students.

Dietary Intake: During 3-4 week of run-in period prior to the intervention, daily energy requirements for all subjects was determined by estimating resting energy expenditure and multiplying the obtained value by a factor of 1.5 (43). During the run-in period and throughout the intervention, all subjects followed a weight maintenance diet of 50-55% carbohydrate, 20% protein, 25-30% fat. Diet counseling was provided pre-intervention to all subjects to promote healthy eating using the American Heart Association Guidelines (44)

Results

For the study, 145 individuals were screened by phone, 40 completed outpatient screenings and 21 met the criteria for participation. Fourteen boys enrolled and completed the study with excellent attendance (100%). Of these subjects, 4 had prediabetes or impaired glucose tolerace (IGT). Of note, all participants with prediabetes (*n*=4) had normalization of glucose tolerance after the 3-month exercise training program. Below (Tables 14 – 16) are the results of 14 subjects who have completed this study.

Table 14. Summary of Exercise Training Sessions

	Aerobic Exercise	Resistance Exercise	Control
n	6	6	2
Attendance (number of sessions/%)	41 ± 2 (100%)	41 ± 3 (100%)	NA
Duration (minute/session)	58.0 ± 1.1	63.3 ± 2.9	NA
Average heart rate/session	151.8 ± 4.7	NA	NA
Energy expenditure (kcal/session)	687.8 ± 225.6	NA	NA

Mean ± Standard Deviation.

Table 15. Summary of Computerized Analysis of Self-Reported Food Intake During the Intervention

	Aerobic Exercise	Resistance Exercise	Control
n	6	6	2
Energy intake (kcal/day)	1943 ± 225	2120 ± 494	2196 ± 139
Fat intake (% of total)	32.9 ± 5.1	33.7 ± 3.2	34.2 ± 0.2
Carbohydrate intake (% of total)	51.2 ± 5.4	51.0 ± 3.5	51.1 ± 0.1
Protein intake (% of total)	15.9 ± 1.2	15.3 ± 1.7	14.7 ± 0.4
Number of dietary record submitted	45.5 ± 8.1	44.3 ± 6.5	23 ± 5.7 *

Mean ± Standard Deviation.

* Significantly different from other groups, $P<0.01$.

Table 16. Subject Characteristics

	Aerobic Exercise (*n*=6)		Resistance Exercise (*n*=6)		Control (*n*=2) ‡	
	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention
Age, yr	14.7 ± 2.0		14.0 ± 1.1		14.6 ± 0.6	
Body weight, kg	102.2 ± 22.9	103.4 ± 17.8	93.0 ± 7.5	93.3 ± 8.1	99.4 ± 6.9	103.7 ± 9.7
BMI, kg/m^2	35.1 ± 5.3	35.2 ± 4.2	34.7 ± 1.0	34.3 ± 1.7	33.2 ± 1.7	34.0 ± 2.5
Body fat, %	39.1 ± 2.3	38.6 ± 2.4	**41.9 ± 2.9**	**39.5 ± 4.2 ***	43.1 ± 9.1	43.9 ± 7.9
Fat mass, kg	39.1 ± 8.2	39.0 ± 5.4	37.9 ± 3.7	36.2 ± 4.1	43.0 ± 12.3	45.0 ± 11.6
Fat free mass, kg	61.3 ± 14.4	62.8 ± 12.5	**52.8 ± 5.9**	**55.6 ± 7.0 ***	56.0 ± 4.8	57.0 ± 3.3
Waist circ, cm	103.0 ± 10.8	102.6 ± 6.7	100.4 ± 3.5	98.2 ± 2.9	102.3 ± 5.7	103.1 ± 5.6
Midthigh circ, cm	65.8 ± 6.3	65.8 ± 6.0	**64.8 ± 4.6**	**65.7 ± 4.6 ***	65.5 ± 4.1	65.8 ± 4.5
CRF, ml/kg/min	**28.6 ± 2.7**	**38.9 ± 4.1 ***	**28.7 ± 3.8**	**35.0 ± 4.3 ***	27.2 ± 1.2	30.7 ± 4.4
Abdominal AT, cm^2	501.7 ± 89.6	477.6 ± 76.1	**493.9 ± 37.1**	**435.1 ± 36.5 ***	504.0 ± 183.0	551.9 ± 205.3
SAT, cm^2	429.7 ± 85.2	415.9 ± 72.4	**421.8 ± 51.8**	**383.7 ± 30.6 ***	424.4 ± 163.4	452.8 ± 193.5
Visceral AT, cm^2	72.0 ± 23.4	61.7 ± 20.3	**72.1 ± 31.8**	**51.4 ± 25.2 ***	79.6 ± 19.6	99.2 ± 11.8
Fasting glucose, mg/dl	93.5 ± 7.2	94.0 ± 6.4	92.2 ± 5.3	93.0 ± 11.5	100.5 ± 2.1	93.0 ± 2.8
Glucose AUC	16163 ± 2217	15178 ± 2346	16243 ± 939	16310 ± 908	14524 ± 1904	14167 ± 626
Glucose disposal (Hyper), mg/kg/min	7.9 ± 3.0	8.3 ± 2.5	7.9 ± 1.7	11.0 ± 4.5 †	9.6 ± 0.4	-
Glucose disposal (Eug), mg/kg/min	6.0 ± 2.5	6.0 ± 2.1	**7.1 ± 1.2**	**9.0 ± 1.4 ***	6.1 ± 0.9	-

Mean ± SD.

Pre-intervention vs. post-intervention within each group: **P*<0.05; †*P*=0.074.

‡ Only 1 subject participated in post-clamp measurement.

This project examined the feasibility of this type of intensive intervention trial in the pediatric settings. Our preliminary findings suggest that regular exercise alone (without calorie restriction), regardless of exercise modality, is beneficial to improve cardiorespiratory fitness in previously sedentary overweight/obese boys. Further, we observed that in the absence of changes in body weight, resistance exercise is associated with significant reductions in total body fat (-2.4%) and visceral (~28%) and abdominal subcutaneous (~9%) AT, and increases in fat free mass (2.8 kg) and insulin sensitivity (39% by hyperglycemic clamp and 26.8% by euglycemic clamp). These preliminary findings were encouraging and provided evidence that regular exercise, in particular resistance exercise, may be an effective strategy to reduce total and abdominal adiposity, and to improve insulin sensitivity in previously sedentary overweight boys. Pilot findings also provided a rationale for further investigating the effects of exercise training on obesity, fitness, and type 2 diabetes.

2.4 IMPLEMENT THE JOSLIN VISION NETWORK ARCHING SYSTEM AT WHMC

2.4.1 Expand Image Reading Center at WHMC

Diabetic retinopathy is the leading cause of new cases of blindness in Americans between the ages of 20 to 74 (45-50). It has been estimated that blindness from diabetic retinopathy is preventable in at least 65% of cases, if abnormalities are identified through screening, before patients become symptomatic. Although retinal laser therapy has been shown to stabilize visual acuity, there is less success at improving or restoring vision that has already been lost (48). Unfortunately, retinal screening of diabetics is not consistently performed. Data from the Behavioral Risk Factor Surveillance System (BRFSS) has shown that the rate of eye exams in Pennsylvania ranged from 64.8% and 72.4% depending on age group, from 1994 to 1998, and It has also been estimated that only 77% of the 59 MDW enrolled diabetic population receives the annual recommended eye screening examinations with the screening rate for the entire Air Force Medical Service, 66%, is even lower (51). To improve screening rates and decrease ophthalmologic complications, innovative approaches must be introduced and continually implemented to make eye exams and specialty services more accessible, particularly to patients in under-served and geographically isolated locations (51). New technology allows non-dilated examinations to be conducted by personnel within primary care practice sites, with images transmitted electronically to specialists for interpretation.

Prior efforts have demonstrated that teleophthalmology and retinal imaging have significant impact for the military. SGR has approved and prioritized an unfunded Modernization Directorate requirement “Ocular Telemedicine in Retinal Screening for Diabetic Retinopathy” (submitted Dec 03 by AETC as sponsor, submitted by LtCol (Dr.) Gary Lane, SGR tracking # 20031009). This SGROCC validated requirement provides the logical follow-on and sustainability for the initial efforts in instituting a reading imaging center as well as ensuring the appropriate infrastructure is in place at 59 MDW. With increasing deployment requirements, completion of military service obligation, and other training cycle variables affecting manpower distribution, the number and distribution of qualified military eye care specialists continues to be reduced.

Digital fundus imaging in primary care clinics at outlying bases helps to fill this gap. Patients at remote sites are able to receive high quality digital retinal photo-screenings which are a tremendous patient management tool to maximize limited ophthalmology staffing. This retinal imaging teleophthalmology project serves as the template for an Air Force-wide deployment of ophthalmic digital photo-screening capability, allowing individuals stationed at remote sites to have access to a retinal exam, evaluated by

experts at one or more central reading centers. Although digital images and telemedicine are not new, this project in coordination with prior efforts encompassed the review of integrating a comprehensive screening and image reading center, inclusive of image transfer and archival mechanisms, into the ophthalmic standard of care for the Air Force Medical Service (AFMS).

The direct electronic transfer, as well as the archival mechanism for retinal images is essential for this model of care to scale and deploy throughout the AFMS. Below outlines the various components in establishing this information technology structure.

Essential Training for Retinal Team

As described in *Focus Area 2, goal 1a, Submit interim report to SGR providing detail of training providing to Retinal Team*, WHMC ophthalmologist, Stephen Waller MD, worked with the UPMC and Joslin Diabetes Center to establish a knowledge base and resource dissemination at WHMC Reading Center. A component of this educational program was an infrastructure for provider education. Provider educational efforts were concentrated in spring and summer 2006 and continued locally via Dr. Waller serving as the lead educator. The education focused on information dissemination, and participation in clinical domain specific summits. Additionally, upon the integration of each information technology tool, the expectation is for each provider responsible for its use would engage in vendor specific training. This includes training for both CDMP, as well as an additional session with JVN. Due to the late implementation of JVN and full integration with CDMP, the Dr. Waller and his team hadn't participated in the secondary JVN training.

Image Reading Center Development and Implementation

As described in *Focus Area 2, goal 1b, Submit final report to SGR on Image Reading Center development and implementation; report will provide data analysis using percent enrolled diabetics who receive annual diabetic exams as a metric*, UPMC in collaboration with Dr. Waller and AFMS, established a comprehensive retinal screening program that improved access to care and enhanced prevention strategies of vision loss. This was achieved through the utilization of clinical resources, appropriate education, and access to an at risk population. Effective image collection processes were developed to ensure timely and accurate reading of retinal images by a medically trained ophthalmologist. Pre-defined image collection processes were translated into collection process for clinic(s) located in the San Antonio area participating in this retinal imaging study. This process, initially workable, continues to evolve with the recent integration of JVN and CDMP.

2.4.2 59 MDW Implementation of CDMP-Compatible Digital Photo Viewing and the JVN, Archiving System

Interim Report that Reviews the Challenges and Shortfalls with the Utilization and Outlines a Summary Discussion for 59 MDW Leadership and UPMC

CDMP, an efficient disease management software tool that includes integrated eye care management, JVN is based on the Chronic Care Model. This web-based software application is used to manage patients with chronic illnesses, such as Diabetes. At WHMC, CDMP interfaces with the Integrated Clinical Database (ICDB). ICDB is an electronic medical record with patient information such as lab values, patient appointments, etc. CDMP is specifically designed for diabetes management and can be

configured for individual users like diabetic educators, endocrinologist, ophthalmologists, etc. It is a patient centered system built on available technologies and tools. It uses both behavioral and clinical data to present a healthcare provider with a "whole patient" picture, making it ideal for the use in caring for a diabetic patient population.

As described in Focus Area 2, goal 2a, *Interim report that reviews the challenges and shortfalls with the utilization and outlines a summary discussion for 59 MDW leadership and UPMC*, utilization of CDMP-JVN for retinal screening, reading, and archiving commenced following arduous task of obtaining the appropriate information technology approvals as noted in Focus Area 2, goal 2b. Additionally prior to utilization, UPMC coordinated with AFMS to acquire the necessary infrastructure for the JVN reading station which included large desktop computer, two large flat screens, a single small screen, and an old-fashioned CRT displayed

Following implementation, Dr. Waller and Mr. James Mason coordinated with WHMC Radiology Service Administrator to obtain space on a local server. Additional efforts have been to understand how best to attach the Jpeg image files to electronic records within AHLTA, as well as, connect multiple cameras without losing continuity of information obtained previously and having the ultimate goal to view images taken at remote locations, such as Laughlin.

Final Report to SGR on Challenges and Shortfalls of Process to Implement System(s)

As described in Focus Area 2, goal 2b, *Final report to SGR on challenges and shortfalls of process to implement system(s)*, CDMP was ultimately installed at WHMC Diabetes Outreach Clinic (DOC) May 2007. Upon commencing efforts to install CDMP, challenges primarily associated with Information Technology Security evolved requiring significant effort to resolve. Ultimately success was achieved for implementation at WHMC in May 2007. Following initial implementation, UPMC identified many providers had concern with its use. Specifically, CDMP only communicates with ICDB and has limited capabilities for data retrieval. Presently, AFMS requires all providers to us AHLTA for charting on their respective patients. Subsequently, the lack of an interface between CDMP and AHLTA results in duplicative entry (i.e. AHLTA and CDMP) with CDMP being manual entry. Additionally, other barriers often associated with installation of system solutions, were identified by the UPMC team and subsequently addressed in coordination with AFMS and Estenda Solutions. In an effort to resolve such barriers, UPMC worked with AFMS and Estenda Solutions to upgrade CDMP for inclusion of various resources.

Respective utilization of CDMP for the ophthalmology efforts, our major barrier was lack of capability afforded in the CDMP. Initial expectations were the immediate integration of JVN as a component of CDMP. However, in working with the AFMS, it became known that the initial DoD Information Technology Security Certification and Accreditation Process (DITSCAP) acquired for CDMP could not apply to the JVN software tool and its respective installation. An additional DoD Information and Assurance Certification and Accreditation process (DIACAP) was necessary to install JVN.

Despite the above noted operational challenges, one positive aspect was the engagement of the Test Bed and its respective committee to help shepherd the follow-on DIACAP process, as well as the necessary testing to proactively address issues that otherwise would only originate following implementation.

3. KEY RESEARCH ACCOMPLISHMENTS

3.1 Pediatric Diabetes Prevention and Treatment Programs in Western Pennsylvania

- Recognition of CHP as a leader in comprehensive management of childhood and adolescent obesity.
- Development and implementation of an evidenced-based weight management and wellness program that attracts referrals from a previously underserved clinical area.
- Provision of obesity-related treatment to more than 4,250 children and adolescents.
- Development of the Research Registry to monitor WMWC clinical outcomes, learn about obesity phenotypes, conduct retrospective research studies, and recruit for prospective studies on obesity and related conditions.
- Recruitment of 1,083 participants into the Research Registry.
- Reduction in BMI percentile for 70% of children and adolescents.
- Development and testing of an intensive theory-based small group intervention program, which enabled us to identify and refine processes to support future programmatic efforts.

3.2 Pediatric Diabetes Prevention and Treatment Programs at WHMC

- Translation and implementation of CHP's weight management program for treatment of pediatric obesity in a military healthcare beneficiary population.
- Provision of obesity-related treatment to 140 children and adolescents.
- Determination of a population of approximately 10,000 military healthcare beneficiaries who would benefit from our pediatric weight management program at WHMC.
- Development and dissemination of promotional materials to increase clinical referrals to the SAMPC Pediatric Wellness Center.
- Establishment of relationships with Lackland Air Force Base youth programs, including Fit Factor.
- Development and implementation of a pediatric diabetes education program for WHMC to improve diabetes care.
- Attainment of ADA Recognition for the WHMC pediatric diabetes education program, which ensures that it complies with ADA standards and meets Medicare criteria for reimbursement, thereby creating a mechanism to support sustainability of much needed health care services.
- Assessment of pediatric diabetic patient needs for and favorable responses to the pediatric diabetes education program.
- Establishment of evaluation methods to monitor patient compliance to and outcomes of participation in the pediatric diabetes education program.
- Preparation of a business case analysis to support recommendations for a Center of Excellence in Pediatric Diabetes at WHMC.

3.3 Feasibility Studies

- Development and implementation of a system of physician education about childhood obesity through academic detailing.
- Measurement of an academic detailing program upon the frequency and quality of obesity-related counseling, and upon weight of overweight and obese children who receive counseling from trained physicians.

- Determination of feasibility of a randomized controlled trial to examine the independent effect of regular physical activity on risk factors leading to type 2 diabetes and insulin resistance.
- Provision of preliminary evidence that regular exercise, in particular resistance exercise, may be an effective strategy to reduce total and abdominal adiposity, and to improve insulin sensitivity in previously sedentary overweight boys, and a rationale for further investigating the effects of exercise training on obesity, fitness, and type 2 diabetes.

3.4 Implement the Joslin Vision Network Arching System at WHMC

- Continued to develop reading center at 59 MDW through increased education and knowledge.
- Implemented CDMP-JVN teleopthalmology system at 59 MDW through direct interface with other patient care systems.
- Ensured continuum of training among provider and clinicians.
- Expanded resources of 59 MDW image reading center to other remote locations.
- Continued development of protocol for reading/reporting of screening results and diabetic retinopathy patient follow-up.
- Reviewed percent of enrolled diabetics who receive and annual diabetic eye exam, initially monthly and quarterly, followed by cumulative.
- Coordinated with Estenda and AFMS to acquire DITSCAP and DIACAP approvals for CDMP and JVN, respectively.
- Integrated and deployed CDMP/JVN at 59 MDW.
- Trained providers for efficient use of CDMP/JVN both locally and nationally (i.e. Joslin, Boston)
- Assessed successes and shortfalls of implementing CDMP/JVN at 59 MDW.

4. REPORTABLE OUTCOMES

4.1 Manuscripts, Abstracts, and Presentations

All publications and presentations listed in this section were completed, in whole or in part, by UPMC and CHP project staff in relation to this award.

- Hannon TS, Rao G, Arslanian SA. Childhood obesity and type 2 diabetes. *Pediatrics* 116: 473-80, 2005.
- Rao G. Pediatric obesity-related counseling in the outpatient setting. *Ambulatory Pediatrics* 5: 377-9, 2005.
- Hannon TS, Arslanian SA. Obesity and type 2 diabetes mellitus in adolescents: what is new? *Current Opinion in Endocrinology and Diabetes* 96: 111-18, 2006.
- Hannon TS, Gungor N, Arslanian SA. Type 2 diabetes in children and adolescents: a review for the primary care provider. *Pediatric Annals* 35: 880-7, 2006.
- Rao G. Child Obesity (overview). Heart Niagara Annual Meeting, St. Catharines, Ontario, Canada. September 19, 2006. Plenary Speaker.
- Rao G. Weight Management in Community-Based Practices. Children's Community Pediatrics – Seminar, Cranberry, PA. October 3, 2006.
- Rao G. Childhood Obesity and the Built Environment. Children’s Hospital of Pittsburgh Environmental Health Conference, Pittsburgh, PA. October 21, 2006.

- Rao G. Child Obesity (overview). Mini Med School – University of Pittsburgh School of Medicine, Pittsburgh, PA. May 2, 2006.
- Rao G. Childhood Obesity: Practical Solutions for a Growing Epidemic. Heart Niagara Annual Meeting, St. Catharines, Ontario, Canada. February 2007. Plenary Speaker.
- Rao G. Weight Management in Primary Care. Altoona Community Physicians, Hollidaysburg, PA. March 29, 2007.
- Rao G. Childhood Obesity: Tackling the Problem in Primary Care. St. Vincent's Hospital Grand Rounds, Erie, PA. July 20, 2007.
- Rao G. Childhood Obesity: Practical Primary Care Approaches. AAFP Infant, Child, and Adolescent Medicine Conference, San Francisco, CA. November 7, 2007.
- Hannon TS, Rofey DL, Hull E Vanderbilt-Adriance E, Arslanian SA. Obstructive sleep apnea and cognitive functioning in adolescents who are overweight. Poster Presentation. *The Obesity Society* Annual Meeting, 2008.
- Kirkland KS, Hannon TS, Rao G, Rofey D, Bacha F, Libman IM, Arslanian SA. Application of Geographic Information Systems (GIS) mapping in a pediatric obesity center. *Pediatric Academic Societies'*Annual Meeting, 2008.
- Rao G. Child obesity. Highlights of AMA Expert Committee recommendations. *American Family Physician* 78: 56-66, 2008.
- Rofey DL, Szigethy EM, Noll RB, Dahl RE, Lobst E, Arslanian SA. Cognitive-behavioral therapy for physical and emotional disturbances in adolescents with polycystic ovary syndrome: a pilot study. *Journal of Pediatric Psychology* 34: 156-63, 2008.
- Candido C, Bacha F, Hannon TS, Libman L, Arslanian SA. "Obesity and Type 2 Diabetes in Children" in Therapy for Diabetes Mellitus and Related Disorders, 4th Edition, American Diabetes Association, 2008.
- Rao G. Childhood Obesity: Practical Primary Care Approaches. St. Vincent's Hospital, Invited Lecture Maternal-Child Health Seminar, Erie, PA. May 12, 2008.
- Rao G. Childhood Obesity: Practical Primary Care Approaches. Uniontown Hospital Grand Rounds, Uniontown, PA. December 3, 2008.
- Rao G. Childhood Obesity: Practical Primary Care Approaches. UPMC St. Margaret Hospital Grand Rounds, UPMC St. Margaret, Pittsburgh, PA. May 21, 2009.
- Rao G. Adolescent Obesity Counseling in the Office Setting. National Initiative for Children's Healthcare Quality Q-Care. (Q-Call through NICHQ/Harvard School of Public Health, Boston, MA). June 12, 2009.
- Rao G. Healthy Living: Lessons from Childhood Obesity. University of Pittsburgh School of Dental Medicine Invited Lecture, Pittsburgh, PA. August 25, 2009.
- Rao G. Pediatric Obesity: Practical Primary Care Approaches. University of Leeds Invited Lecture, Leeds, West Yorkshire, United Kingdom. September 12, 2009.
- Rao G. Maternal-Child Health Update: Pediatric Obesity: Practical Primary Care Approaches. Altoona General Hospital, Altoona, PA. September 24, 2009.
- Hannon TS, Lee SJ, Chakravorty S, Lin Y, Arslanian SA. Obesity and obstructive sleep apnea in adolescents: relationships to visceral adiposity. Submitted to the *Journal of Pediatrics*; under review.
- Hannon TS, Rofey DL, Hull EE, Kolko RP, Chakravorty S, Lin Y, Arslanian SA. Obstructive sleep apnea and cognitive functioning in adolescent obesity. Submitted to the *Journal of Pediatrics*; under review.

4.2 Informatics

WMWC Research Registry (Described in Section 2.1.2)

4.3 Funding Applied for Based on Work Supported by the Award

- Ingrid Libman M.D. Ph.D: *Are Overweight Children with Type 1 Diabetes (T1DM) at increased risk of cardiovascular disease?* (NIH K23 HL08528).
- So Jung Lee Ph.D: *Physical Activity in Youth: Implications for reversing risk factors for cardiovascular disease and type 2 diabetes mellitus.* (American Diabetes Association Junior Faculty Award).
- Dana Rofey, Ph.D.: *Healthy Bodies, Healthy Minds: Helping Adolescents with PCOS* (NIH K23 HD061598091).
- Tamara Hannon, M.D.: *Impaired Sleep, Insulin Action and Overweight in Youth* (NIH R03 HD057532 and The Pittsburgh Foundation).
- Stephen Burns, Ph.D.: *Fat Metabolism After a Meal in Overweight Black versus White Adolescents: Effects of a Single Bout of Exercise* (Thrasher Research Fund).
- Fida Bacha M.D.: *Insulin Secretion, Insulin Action and Cardiovascular Disease Risk Assessment in Youth with T2DM* (Thrasher Research Fund).
- Fida Bacha, M.D.: *Fetal Origins of Childhood Insulin Resistance and Risk of T2DM* (NIH R03 HD059798 (priority score 198, was resubmitted June 2009).

5. CONCLUSIONS

To address the national public health priority of reducing the incidence of diabetes and alleviate its complications, we focused our efforts on diabetes prevention and treatment programs for civilian and military populations. Specifically, we (1) developed and implemented an evidence-based pediatric weight management program to help youth and families in Pennsylvania and in the Air Force adopt a healthy lifestyle in order to maintain and achieve a healthy weight, (2) established a pediatric diabetes education program for WHMC to improve diabetes care, and (3) andimplement and deploy JVN at WHMC Diabetes Eye Image Center. Project evolution and success relied significantly on the collaboration among UPMC, CHP, UPDI, and US AF SGR-M and illuminated elements of the core infrastructure needed to implement a scalable and customizable national model for prevention and treatment.

Throughout the course of this initiative, we encountered a series of challenges that often hindered our efforts form both an administrative and programmatic focus. These range from an evolving health care environment to more familiar barriers often encountered when participating in translational research studies. Our challenges are bulleted below.

- The dynamic nature of health care and addressing chronic disease.
- Delays in hiring staff, particularly at WHMC. At the start of the project, the United States was beginning to experience a shortage of diabetes health care professionals, endocrinologists, primary care physicians, nurses, and diabetes educators. This shortage escalated throughout the course of the project period, making it extremely difficult to recruit clinical and research personnel.

- Staff turn-over
- Lack of clarity regarding reporting strategies and documents.
- Recruitment challenges, particularly in rural and underserved communities.
- Managing a personnel and clinic in Texas from a long-distance (Pittsburgh).
- Expected challenges in translational research.

These challenges impacted our efforts in a variety of ways. Delays in hiring of staff at WHMC limited the number of patients treated at the SAMPC Pediatric Wellness Center and the WHMC pediatric diabetes education program, as well as limited the longitudinal assessment of the latter program during the award period. Translational research challenges were evident in the testing of the pediatric weight management intensive group intervention program and the academic detailing study. High rates of attrition in the group intervention program and limited consent for chart review in the academic detailing study precluded rigorous assessment of program effectiveness. However, these challenges should also be viewed as important research findings in that they provide insight into how to improve methodologies for future research and programmatic endeavors.

Notably, this initiative enabled us to establish diabetes prevention and treatment programs that fulfilled a national public health mandate and extended health care services to previously underserved populations. The work accomplished through this award has formed the basis of subsequent efforts to develop sustainable models of diabetes prevention and treatment. We have gained increasing expertise at assessing outcomes of clinical and population-based interventions. Through our monitoring systems and close follow-up and tracking of participants in our diabetes prevention programs, we continuously modify and individualize the obesity and diabetes interventions to optimize delivery of care. Our ultimate objective is to create a prototype of care that can be packaged for third party reimbursement to be used initially locally and later on nationwide. UPMC, CHP, WHMC, and AF SGR continue to refine existing models of care and note the necessity to continually revise strategic direction to assure effective implementation of national prevention and treatment strategies for diabetes.

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