

Running head: BARIATRIC SURGERY

APPROVAL SHEET

Title of Capstone: A Program to Increase Bariatric Surgery Referrals  
Through Clinical Practice Guidelines

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Abstract

Obesity has reached epidemic levels in our country. Clear clinical practice guidelines (CPGs) are available that address identification, evaluation, and treatment of overweight and obese adults. These CPGs are based on the best evidence available and include dietary, exercise, behavioral, pharmacologic, and surgical interventions<sup>1</sup>. Despite these guidelines and data on the efficacy, safety and technical advances of bariatric surgery<sup>2,3</sup>, the overall attitude of patients and providers toward bariatric surgery is negative<sup>4-10</sup>. Although there has been a consistent increase in the number of bariatric surgeries being performed, the numbers are still low compared to the number of obese Americans<sup>11</sup>. There is compelling evidence in favor of bariatric surgery as a treatment for morbid obesity, yet few patients are being referred to bariatric surgeons<sup>3</sup>. One reason that may be is there is a great deal of misinformation about bariatric surgery and many providers have not read or received education treatment of obesity and on bariatric surgery<sup>4-10</sup>. Specifically, referrals from Greater Baltimore Medical Associate (GBMA) providers to the Comprehensive Obesity Management Program (COMP) at Greater Baltimore Medical Center (GBMC) are lower than the national average.

The purpose of this capstone project was to develop a program for Greater Baltimore Medical Associate (GBMA) primary care providers on the clinical practice guidelines for the identification, evaluation, and treatment of overweight and obese adults including bariatric surgery.

Primary care providers from an existing database were surveyed to develop a list of items to include in the education program. Sixty primary care providers were emailed and sixteen providers responded to the internet survey. The majority of the providers selected six of the eleven items to be included in the program. The program was developed based on these recommendations. The program was piloted in two out of fifteen GBMA practices. The

program was advertised to the GBMA providers by email and in a print advertisement in their lounge lunch room. Seven providers attended the program. All of the participants felt the program would improve how they cared for their obese patients and believed that because of the program they were more likely to adhere to the clinical practice guidelines for diagnosis, evaluation and treatment of obesity. Six of seven of the participants felt that the program improved their opinion of bariatric surgery. In addition, all of the participants felt that because of the program they were more likely to refer their obese patients to a bariatric surgeon.

Use of current clinical practice guidelines, simple tools and face-to-face meeting with primary care providers may improve the care of obese patients. This program will be replicated at other GBMA practices and should be considered at other practices locations. Future data collection would be helpful to determine if, in fact, the program does improve the care of obese patients, increase the use of clinical practice guidelines and increase appropriate referrals to bariatric surgeons.

A Program to Increase Bariatric Surgery Referrals  
Through Clinical Practice Guidelines

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## Acknowledgements

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**Background**

Obesity has reached epidemic levels in the United States. According to the Center for Disease Control's 2007 statistics, Colorado was the only state with obesity prevalence rates less than 20% and three states had obesity rates at 30% or greater<sup>12</sup>. In 2005-2006, 34.3% of adult Americans were obese<sup>13</sup>. During 2003-2004 the prevalence of extreme obesity or body mass index (BMI) greater than or equal to 40kg/m<sup>2</sup> was 4.8%, approximately 15 million Americans<sup>14</sup>. It is projected that 51.5% of American adults will be obese by 2030 and that 100% of adults will be obese by 2102<sup>15</sup>.

Obesity is linked to numerous chronic health conditions including hypertension, hyperlipidemia, sleep apnea, type 2 diabetes and heart disease<sup>16</sup>. Obesity-associated conditions significantly increase hospital length of stay, mortality and overall health care costs<sup>17</sup>. A 2003 study found that obesity causes a marked decrease in life expectancy. A 20 year old white male with a BMI greater than 45 kg/m<sup>2</sup> is estimated to have 13 years of life lost compared to the same age and race male with a BMI of 24 kg/m<sup>2</sup><sup>18</sup>. A 20 year old black male with a BMI greater than 45 kg/m<sup>2</sup> is estimated to have 20 years of life lost when compared to the same age and race male with a BMI of 24 kg/m<sup>2</sup><sup>18</sup>. Lakdawalla, Goldman and Shang (2005)<sup>19</sup> found that after age 70 Medicare spends 35 % more on obese patients than their normal weight counterparts. It costs an estimated \$1400 more per year to care for an obese individual than one of normal weight<sup>20</sup>. In addition, there are a multitude of psychosocial aspects affected by obesity such as well-being, quality of life and social stigmatization<sup>21-23</sup>. A leading cause of preventable death, obesity needs to be treated as a chronic health condition by primary care providers.

There are multiple studies investigating patient's knowledge of healthy body weight, obesity, nutrition, exercise, and the effect of body weight on their health<sup>24-28</sup>. Unfortunately, a 2006 study showed that desired body weight is on the rise<sup>29</sup>. Studies have shown that patients

have an altered perception of their body weight, but that obese patients typically identify themselves as obese and are aware of the health risks <sup>30</sup>.

### **Current Clinical Practice Guidelines for Obesity**

Many professional organizations and governmental agencies have statements or guidelines regarding screening, diagnosis and treatment of obesity. The American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the American Diabetes Association and the American College of Preventive Medicine all have recommendations for measurement of height and weight or BMI.

The U.S. Preventative Services Task Force (USPSTF) recommends that all adults are screened for obesity using BMI as the measurement. In addition, they recommend that clinicians offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults <sup>31</sup>. Counseling about diet, exercise, or both, in conjunction with behavioral interventions aimed at skill development, motivation, and support strategies is recommended <sup>31</sup>. In May of 1995, the National Heart, Lung, and Blood Institute's (NHLBI) Obesity Education Initiative in cooperation with the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) convened an expert panel to develop evidence based guidelines for primary care management of obesity. Subsequently, in 1998, the NHLBI published clinical guidelines on the identification, evaluation, and treatment of overweight and obese adults. A systematic review of 394 randomized controlled trials (RCT) was conducted to determine the best evidence regarding obesity management <sup>32</sup>. The panel recommendations were based on evidence that links obesity to increased mortality and evidence that weight loss reduces risk of developing obesity related disease. The guidelines include an assessment and treatment guide and are currently being updated with a proposed publication date in December 2009. In 2000, The Practical Guide to Interventions, Evaluation and Treatment of Overweight and Obesity in Adults

was published to give practitioners a practical guide and tools to assist their patients<sup>1</sup>. The guide includes an algorithm that begins with diet therapy, behavioral therapy, and physical activity and includes consideration of pharmacotherapy and bariatric surgery<sup>1</sup>.

According to the guidelines, assessment of the patient should include BMI, waist circumference and analysis of risk factors. BMI is weight in kilograms divided by height in meters squared and is routinely used to define obesity. Adults with a BMI over 25 kg/m<sup>2</sup> are considered overweight and those with a BMI over 30 kg/m<sup>2</sup> are considered obese. Table 1 further shows the diagnostic classifications for weight based on BMI<sup>32</sup>. Waist circumference greater than 40 inches in males and 35 inches in females is an independent risk factor for obesity related complications in patients with BMI of 25 to 34.9 kg/m<sup>2</sup>. In addition, risk factors for potential obesity related mortality and morbidity should be determined. Presence of disease conditions or risk factors such as type 2 diabetes, sleep apnea, hypertension and physical inactivity increase the patient risk of obesity related sequelae. This increased risk status should lower a practitioner's threshold for initiating weight loss treatment. All patients with a BMI of  $\geq 30$  kg/m<sup>2</sup> or patients with a BMI of  $\geq 25$  kg/m<sup>2</sup> with a waist circumference risk factor and  $\geq 2$  other risk factors should be assisted with developing weight related goals and treatment.

The treatment algorithm begins with diet therapy, behavioral therapy, and physical activity and includes consideration of pharmacotherapy and bariatric surgery<sup>32</sup>. Diet therapy should consist of a 500-1000 calorie daily deficit by reduction of both fat and carbohydrate. Physical activity should be initiated in all patients and should progress to reach 30 minutes on most days of the week. Behavioral therapy should ideally be combined with diet and exercise and include strategies for compliance. Pharmacotherapy should be considered in patients with BMI  $\geq 27$  kg/m<sup>2</sup> with risk factors and in those with BMI  $\geq 30$  kg/m<sup>2</sup> with no risk factors. Sibutramine (Meridia<sup>TM</sup>) and orlistat (Xenical<sup>TM</sup>) are FDA approved prescriptions drugs

available for long-term treatment of obesity. Since publication of the guidelines, orlistat has been made available in a lower dose over the counter as Alli™. Although phentermine is an FDA prescription drug approved for short-term use, the recommendations only include medications approved for long term use due to the chronic nature of obesity. Weight loss medications must be used in select patients and need to be monitored closely by providers. Dietary, behavioral and exercise interventions have limited data that validates long-term efficacy<sup>33,34</sup>. High recidivism rates make frequent follow-up crucial in these patients<sup>32-34</sup>. According to the practical guide, “if attempts to lose weight have failed, and the BMI is  $\geq 40 \text{ kg/m}^2$ , or 35 to 39.9  $\text{kg/m}^2$  with comorbidities or significant reduction in quality of life, surgical therapy should be considered”<sup>1</sup>.

### **Current Provider Practice in Obesity Treatment**

Despite the growing concern over health consequences of obesity, there is an abundance of documentation about lack of knowledge and failure of primary care providers to identify and treat obesity<sup>35,36</sup>. Physicians identified obesity in 38% of their obese patients and only 36% of those patients were counseled on weight loss according to data from the National Ambulatory Medical Care Survey<sup>35</sup>. Galuska et al. (1999) found that 42% of obese adults recall getting advice regard diet from a health care provider. In the same study, patients who were told to lose weight were 3 times more likely to attempt to lose weight than those not told to lose weight . In a 2003 study on the knowledge and attitudes of internal medicine residents on obesity, 60% did not know the BMI for diagnosing obesity and 69% did not recognize waist circumference as a measurement tool for obesity. Less than one-third of the residents in the study reported success in treating obesity and nearly half incorrectly reported their own BMI<sup>37</sup>. A 2004 study shows that providers are still remiss in recommending weight loss to their morbidly obese patients but those who recommended weight loss surgery were more likely to have previously recommended

other weight loss interventions<sup>38</sup>. Crow et al. (2004) reported that of the three main components of the NHLBI guidelines, physicians always offered weight loss diets 31.2% of the time, behavioral modification 1.2% of the time and exercise prescriptions 36.5% of the time. Nearly 35% of physicians never offered weight loss medications and 44.2% never offered referral for gastric bypass.

### **Problem Statement**

Despite a large increase in the use of bariatric surgery in the United States, the percentage of morbidly obese patients having surgery is still low<sup>39</sup>. It is estimated that 180,000 patients had bariatric surgery in 2006<sup>14</sup>. Accounting for only patients with BMI of 40 kg/m<sup>2</sup>, less than 1.5% of the patients that qualified for bariatric surgery actually had surgery.

Greater Baltimore Medical Center (GBMC) collects data on provider referrals. Providers, for the purposes of this project, are considered physicians, nurse practitioners and physician's assistants. Data is collect on referrals from providers to other providers and departments throughout the health care system. Greater Baltimore Medical Associates (GBMA) is a large group of physician practices owned by GBMC. Monthly tracking reports indicate that referrals from GBMA providers to the Comprehensive Obesity Management Program (COMP) for a consultation with a bariatric surgeon are low. Monthly referrals range from zero to one, yet 30-60 patients attend information sessions about bariatric surgery each month indicating that GBMA providers are not referring their patients to the COMP.

### **Purpose of the Project**

Research indicates that providers who are less familiar with obesity treatment guidelines are less likely to refer to bariatric surgeons<sup>4</sup>. The purpose of this project was to develop a program for primary providers to familiarize them with current clinical practice guidelines (CPG) for the identification, evaluation and treatment of obesity, thereby increasing adherence to

the obesity CPGs and referrals to the COMP. The program was developed based on the best evidence for identification, evaluation and treatment of obesity and the best evidence in educating providers on clinical practice guidelines. The program was piloted in GBMA internal medicine, primary care, family practice and gynecology offices.

### **Theoretic Framework**

Successful adoption of any new clinical behavior is multifactoral<sup>40</sup>. Clearly, the research on obesity management and bariatric surgery referrals points to a variety of reasons why clinical practice guidelines are not being followed. Best practice research on how to diffuse obesity management and bariatric surgery information into clinical practice is limited. Rogers' Diffusion of Innovation model (fig. 1) is one theoretical approach useful in guiding the process of making a change in clinical practice. This theory was used to direct the process for the education program for the providers at GBMC.

The theory states that five elements play a role in whether or not a change occurs: relative advantage, compatibility, complexity, triability and observability<sup>41</sup>. Relative advantage refers to the perception of whether the change in practice is better than current practice. The program included clear statistics and recent data on why a change to following clinical practice guidelines is better than current practice. Rogers defines compatibility as how compatible the change is with the current beliefs, experiences and needs of the provider. Giving providers concrete examples of how they may fit obesity clinical practice guidelines into their practice is important. Complexity is the degree of difficulty that the provider perceives in understanding or implementing the practice change. While the practice guidelines are quite detailed, there is a simple algorithm that can be followed. Providers were given a copy of *The Practical Guide: Identification, Evaluation and Treatment of Overweight and Obesity in Adults* to refer to in their daily practice. Triability refers to whether or not providers can trial the practice change and then

evaluate its acceptability to patients and examine potential outcomes. Because following this practice guideline did incur no cost to the providers, it should be easy for them to trial in their practice. Observability refers to the whether or not the results of the change are visible to others. A visible change in practice pattern will increase communication about the change. Although providers already knew that referral data was being collected, the knowledge that someone is actually looking at the data may encourage the practice change through positive feedback.

In addition, the theory states that there are five steps: knowledge, persuasion, decision, implementation, and confirmation. Knowledge is acquired by researchers about the proposed practice change, the provider must then be persuaded to make the change and then make a decision to adopt or reject the change, the provider then implements the change and finally the provider decides whether or not to continue the practice and seeks confirmation from peers about the practice change <sup>41</sup>. Not everyone accepts innovation or makes change at the same rate. Those that do adopt innovation are also divided into five categories: innovators, early adopters, early majority, late majority, and laggards. Rogers also theorizes that not all stakeholders who are persuading providers to change practice have the same influence over adopters. Physicians may be more likely to be persuaded by a peer physician than an allied health colleague and vice versa which is why support from physician colleagues is important <sup>42</sup>. This correlates with Hay and colleagues' data that indicated physicians prefer to make clinical decisions after input from trust colleagues rather than guidelines. While many physicians consider nurse practitioners colleagues, a bit of ambivalence remains about the profession <sup>43,44</sup>.

### **Literature Review**

A comprehensive review of the literature related to the topic included: 1) attitudes of patients and providers toward bariatric surgery, 2) bariatric surgery safety and efficacy, and 3) insurance coverage, cost and inequality in bariatric surgery.

### **Attitudes of Patients and Providers toward Bariatric Surgery**

Patient and provider knowledge and attitudes toward obesity are well documented, but studies on patient and provider attitudes toward bariatric surgery are few. The research that is available is recent. In November and December of 2007, a literature review was conducted to examine the research available on patient and provider attitudes regarding bariatric surgery. A search was performed using MEDLINE, CINAHL, the Cochrane Library databases, Psychology and Behavioral Sciences Collection, Social Sciences Citation Index, ScienceDirect and Academic Search Premier. The main search terms were *obesity surgery*, *gastric bypass*, *bariatric*, and/or *weight loss surgery*. The results were combined with the term *attitude*. The search was limited to the English language. The table of contents of *Surgery for Obesity and Related Diseases*, *Obesity Surgery*, and *Obesity Research* were manually searched for articles. Seventy-eight articles were obtained meeting those search criteria. Articles were excluded if they met any of the following:

1. a commentary or a letter to the editor
2. a review article or an article describing publication elsewhere
3. a survey pertaining solely to attitudes regarding obesity as a disease not bariatric surgery
4. a survey solely of bariatric surgeons' attitudes on types of bariatric surgery
5. a survey of patients' perceptions of provider attitudes
6. a survey of patients' attitude after bariatric surgery

Of the 78 articles retrieved, 70 were excluded. Of the remaining eight articles, 7 were related to provider attitudes and one was related to patient attitudes. The seven provider articles are listed in Table 2 in alphabetical order along with their date of publication, type of survey, sample size,

response rate, number of respondents, sample size calculation, and reliability and validity of survey tools.

Lynch et al. (2007) published a qualitative study of African American female patient attitudes toward obesity and bariatric surgery. The findings showed that the participants felt that they had lack of time and resources for weight loss, described a feeling of lack of control regarding food and identified with a larger body image. They had fears and concerns about bariatric surgery and felt that it was too extreme. Patients perceived bariatric surgery as an extreme measure that should only be used in life or death situations.

Avidor, Still, Brunner, Buchwald, and Buchwald completed a study on 478 physicians in six specialty areas<sup>4</sup>. They found that their sample prescribed bariatric surgery as a treatment to 15.4 % of their morbid obese patients. Seventy-one percent had referred a patient within the last year for bariatric surgery, but 46% of them stated that the referral was typically prompted by the patient. The top two reasons that they did refer patients for surgery were to achieve maintenance of weight loss (40.3%) and for reduction of comorbidities (26.9%). Sixty percent of participants listed surgical risk as the major disadvantage of surgery followed by 25% listing long term complications such as weight regain, dumping syndrome and other side effects. Thirty-seven percent of participants indicated that they did not refer patients because they were not acquainted with a local surgeon. The remaining reasons for not referring, listed in order from highest response rate, were lack of patient interest, their morbidly obese patients do not meet the criteria, amount of “leg work”, preference to treat patients themselves, not believing in referral to bariatric surgeons and that most of their patients meeting the criteria would not benefit from the surgery long term. The participants believed that bariatric surgery was effective long-term for 49% of their patients who had had bariatric surgery. On a 5-point Likert scale the respondents averaged 2.9 in regard to their familiarity to the National Institutes of Health (NIH) guidelines.

The incongruence between the perceived success rate and the reported prescription of bariatric surgery is note worthy. Nearly 50% report it as effective for their patients, yet they only prescribe it to 15% of their patients.

In Balduf & Farrell's (2008) survey of 611 family practitioners and internists, 84% of participants felt they had been unsuccessful at helping severely obese patients lose weight, yet 76% had referred at least one patient for bariatric surgery. Of those 76%, 53% of them stated that the referral was prompted by the patient. Eight-two percent of the participants had patients who had requested referrals to bariatric surgeons. Thirty-five percent felt that they did not have adequate resources to care for bariatric patients and 45% felt competent to deal with the medical complications of bariatric surgery. Eighty-five percent of them had cared for a patient who had bariatric surgery within the past year. Forty-four percent incorrectly believed that the mortality rates for bariatric surgery were 3-4%. Twelve percent reported having read the NIH guidelines regarding treatment of obesity. Forty-six percent of the participants completed continuing medical education (CME) on bariatric surgery within the past year. Providers who referred to bariatric surgeons were more likely to have attended CME on bariatric surgery, were younger and had a higher BMI.

Foster et al. (2003) surveyed 5000 family physicians regarding attitudes on obesity. The survey also asked the participants whether they would recommend patients with a BMI of 40 kg/m<sup>2</sup> and comorbidities to be evaluated by a bariatric surgeon. Only 23% of the respondents said they would recommend an evaluation.

Respondents to a survey of 620 family physicians by Perlman, Reinhold, and Nadzam (2007) had an average of 19 years of experience. Eighty-five percent had referred patients for gastric bypass (GBP). Fear of complications and perceived high death rate were given as the primary reasons for not referring patients for surgery. Thirty-five percent of the participants did

not refer patients because they believed that their patients would be unable to follow the post-operative lifestyle. Six percent believed that obesity was best controlled by surgery. Most physicians were able to correctly state BMI criteria for surgery, but many incorrectly stated estimated weight loss by GBP. Seventy-seven percent underestimated weight loss while 8 percent overestimated weight loss. Sixty-three percent would refer themselves or family members to a bariatric surgeon if needed.

In a survey of 246 internal medicine, family medicine and obstetrics/gynecology medical staff, Sansone, McDonald, Wiederman, and Ferreira (2007) reported data on attitudes of providers regarding GBP surgery. The mean years of medical practice since residency was 16.73. Eight-four percent of the providers would recommend GBP for morbidly obese patients and 22% of them felt that it was the only effective means for treating morbid obesity. Female providers were statistically less likely to refer patients for surgery than males. Seventy-seven percent of them felt that patients were screened appropriately for surgery, yet 63% felt that surgery is over-utilized in the medical community today. Sixty-nine percent of them believed that GBP patients seem to have a high rate of post-operative complications, but 64% of them felt that GBP saves society money in the long run. Neither age, years in practice nor personal obesity had a significant impact on bariatric surgery recommendation. Male physicians, though, were more likely to refer patients to bariatric surgeons than female physicians.

Schuster, Morton, Liu, Alami, and Curet (2006) surveyed 61 medical students regarding their attitude toward obesity and bariatric surgery. Forty-four percent indicated that they would consider a career in bariatric surgery and 70% stated they would consider performing bariatric surgery as part of their practice. Eighty-nine percent of those surveyed would recommend bariatric surgery to a family member and 77% would have surgery themselves if needed. This

may indicate that current medical school education has increased its emphasis on obesity and obesity treatment.

Thuan & Avignon (2005) surveyed 744 French general practitioners on obesity management and their views on bariatrics surgery. Eighty-nine percent of the respondents felt that bariatric surgery should be considered only in exceptional cases. Eighty-seven percent felt that surgery should be restricted to patients who failed other treatments after one year of follow-up. Seventy-five percent felt that only a nutrition specialist should indicate whether or not a patient should have surgery. Seventeen percent either strongly agreed or agreed that surgery was the only option possible for obese patients to significantly reduce and maintain weight loss while 26% strongly disagreed.

#### **Synopsis of the Findings on Patient and Provider Attitudes toward Bariatric Surgery**

A synopsis of the literature on patient attitudes toward bariatric surgery reflects the paucity of research. Because of its qualitative, ethnographic design, Lynch and colleagues' 2007 study of patient attitudes has limited generalizability. The findings showed that the participants felt that they had lack of time and resources for weight loss, described a feeling of lack of control regarding food and identified with a large body image. They had fears and concerns about bariatric surgery and felt that it was too extreme. This data may prompt further research on the attitudes and barriers to bariatric surgery in other populations and prompt research on interventions for obesity.

Analysis and synthesis of the literature on provider attitudes on bariatric surgery is also limited due to the limited number of studies and the variability in the surveys. Four of the seven studies specifically looked at attitudes regarding bariatric surgery. The remaining three addressed attitudes toward obesity management and included a small subset of bariatric surgery. Seldom did researchers ask the same questions in the survey tools used. The literature shows

mixed attitudes toward bariatric surgery. Table 3 describes some similarities among the surveys. Between 71 to 85% of providers have referred patients for bariatric surgery, but 45.5-53% of the referrals were patient initiated. Between 63% and 77% of providers/medical students would consider bariatric surgery themselves and between 63% and 89% of providers/medical students would refer a family member for surgery. The numbers of providers who referred patients meeting criteria for surgery was much broader. Inconsistency was found among the respondents of the surveys and one study posed that this may be due to underlying ambivalence<sup>8</sup>. In addition, there was a good deal of misinformation about bariatric surgery and a low percentage of providers had read or received education on bariatric surgery<sup>4-10</sup>. The overall attitude of patients and providers toward bariatric surgery is inconsistent with research showing its efficacy and safety. Against the backdrop of major obesity problem in the U.S. many questions remain about provider attitudes towards bariatric surgery due to the limited data published. This supports the need to explore this area further and provide essential educational programs.

### **Bariatric Surgery Safety and Efficacy**

Multiple studies, as demonstrated in the Maggard and colleagues' (2005) meta analysis, have shown the safety and efficacy of bariatric surgery. The 2005 meta analysis reviewed the safety and efficacy of bariatric surgery in 147 studies. The meta-analysis showed that bariatric surgery is more effective than non-surgical weight loss treatments for patients with a BMI of 40 kg/m<sup>2</sup> and results in 20-30 kg weight loss that is maintained for up to 10 years. Similar findings were found for patients with BMIs of 35-39.9 kg/m<sup>2</sup>, but could not be considered conclusive. The study also found that current bariatric procedures in use have a mortality of less than 1%.

A 2004 meta-analysis by Buchwald et al. examined 136 studies and included a total of 22094 patients. They found that the overall percentage of excess weight loss (%EWL, the amount of weight lost expressed as a percentage of patient's weight in excess of his or her ideal

weight) for bariatric procedures was 62.1%. Gastric bypass weight loss was 61.6% while gastric banding weight loss was 42.7%. In addition, the  $\leq 30$  day mortality was 0.1% for restrictive procedures and 0.5% for gastric bypass. Nearly 77% of patients had resolution of diabetes and 61.6% of patients had resolution of hypertension. Obstructive sleep apnea resolved in 85.7% of patients and hyperlipidemia resolved in 70% of patients.

According to a 2007 report from the Agency for Healthcare Research and Quality (AHRQ), the death rate from bariatric surgery declined 78.7% from 1998 to 2004. In 1998, the inpatient death rate was 0.89 percent compared to 0.19 percent in 2004<sup>45</sup>). A recent study found that from 2002 to 2006 the complication rate for bariatric surgery dropped 21% despite an increase in the percentage of older and sicker patients. The average number of pre-existing illnesses such as diabetes, high blood pressure and sleep apnea in the bariatric surgery patient population more than doubled. The proportion of patients over 50 having bariatric surgery increased by more than 50%, while the mortality rate remained unchanged<sup>11</sup>.

There are also numerous studies comparing bariatric surgery patients to control groups. A 2004 study showed a reduction in the relative risk of death by 89% when comparing the bariatric surgery group to controls<sup>46</sup>. A more recent study showed that surgical weight loss patients had 72% lower risk of death than the control group<sup>47</sup>. Another study on long-term mortality matched 7925 bariatric surgery patients to an age, sex and BMI matched control group of 7925 severely obese patients<sup>48</sup>. After 7.1 years, mortality in the surgical group was significantly less. Death rates from diseases such as diabetes, heart disease and cancer were particularly lower, but deaths from suicide and accidents were higher in the surgical group.

The Cochrane Collaboration performed a systematic review of bariatric surgery research<sup>49</sup>. Twenty-six studies, of which 23 were randomized controlled trials (RCTs), met the inclusion criteria and were reviewed. The review indicated that bariatric surgery “results in greater weight

loss than conventional treatment, and that the results are maintained at least up to eight years” (p 18). Data showed that at 8 years follow-up post-bariatric surgery patients had lost 21 kg where the non-surgical patients had gained weight. In addition, post-bariatric surgery patients had improvement in quality of life, diabetes and hypertension. These patients were at increased risk of gallbladder disease, heartburn, vomiting, wound infection and death.

### **Insurance Coverage, Cost and Inequality in Bariatric Surgery**

Cost containment, health insurance, access to health care, and health care disparities are concerns for all health care providers. Cost effectiveness modeling has been completed for bariatric surgery. Craig and Tseng (2002) used a deterministic decision model to compare lifetime expected cost and outcomes of bariatric surgery verses no treatment. The patients had a BMI of  $>40 \text{ kg/m}^2$  and no comorbidities. Their study and other studies have found bariatric surgery to be cost-effective. The cost-effectiveness ratios ranged from \$5000 to \$16,100 per quality-adjusted life year (QALY) for women and from \$10,000 to \$35,600 per QALY for men<sup>50-52</sup>. A recent study looking at health insurance costs of 3600 patients showed that “downstream savings associated with bariatric surgery are estimated to offset the initial costs in 2 to 4 years”<sup>53</sup>.

Insurance coverage for obesity treatment and bariatric surgery has long been debated. Societal stigma and prejudice related to obesity are still present in health care, particularly in the arena of health insurance coverage<sup>54</sup>. A 2007 study at a bariatric surgery center showed that of 1054 patient evaluated for surgery, nearly half underwent surgery. Of the patients that did not have surgery, almost 30% were due to insurance reasons (19.9% were denied by their insurance company and 9.8% had unattainable insurance prerequisites)<sup>55</sup>. The Center for Medicare and Medicaid Services (CMS) issued its decision regarding national coverage for bariatric surgery on

February 21, 2006 deciding that Medicare would pay for bariatric surgery<sup>56</sup>. This decision had huge implications for patients, providers and insurers. Patients covered by Medicare have increased access to bariatric surgery and the average age of bariatric surgery patients rose<sup>11</sup>. In addition, commercial insurers typically follow CMS's reimbursement structure and, therefore, coverage of bariatric surgery will likely increase<sup>56</sup>.

Obesity rates and weight misperception is more common among non-Hispanic blacks and Mexican Americans<sup>57</sup>. Flum, Khan and Dellinger (2007) found that there is also a great deal of racial and financial disparity in bariatric surgery. They found that while African-Americans, Hispanics and the poor are more likely to be obese, they are less likely to have bariatric surgery. Ninety percent of patients who had bariatric surgery were white<sup>58</sup>. In addition to racial inequities, they found that the significant gender and age disparities offer an ethical and public health dilemma as well. A disproportionate amount of surgery was performed on the young while older people account for a large percentage of the obese population<sup>59</sup>. Eighty-four of bariatric surgeries were performed on women<sup>60</sup>. While cultural differences likely play a role, following clinical practice guidelines may help reduce the risk of racial, financial, age and gender disparities.

### **Educating Providers on Clinical Practice Guidelines**

There is a great deal of research on the implementation and adoption of clinical practice guidelines (CPGs), yet studies still show that patients are not getting the recommended care<sup>61</sup>. Reasons for providers' failure to follow clinical guidelines are numerous. Research cites many reasons including varying and conflicting CPGs and lack of time<sup>62,63</sup>. Many methods have been tested to increase provider adherence to CPGs and have had varied success. They include interventions such as formulary restriction, computerized alerts and academic detailing where

peer clinicians use face-to-face social marketing and motivational interviewing techniques to change behavior<sup>42</sup>.

As part of the Cochrane Collaboration, Bero and colleagues (1998) completed an overview of systematic reviews on interventions used to implement research findings. Their conclusion divided interventions into three categories: consistently effective interventions, interventions of variable effectiveness; and interventions that have little or no effect. Educational outreach visits (academic detailing), reminders (manual or computerized) and multifaceted interventions were found to be consistently effective. Audits with feedback or summaries of clinical performance, use of local opinion leaders and local consensus processes have variable effectiveness. Interventions that were found to have little or no effect were distributed education materials and lectures. An overview published in 2001 also reported that educational outreach visits, reminders and multifaceted interventions were most effective<sup>64</sup>.

Another Cochrane Database Systematic Review was completed examining the effect of printed education materials (PEMs) on professional practice and health outcomes. The review found that when compared with no intervention, PEMs did have an effect on provider practice, but not on patient outcomes<sup>65</sup>.

Academic detailing has also been well researched and basic principles have been described. Soumerai and colleagues (1990) list key steps as 1) an assessment of the barriers to the change, 2) a tailored intervention, 3) identification of providers with low adherence and 4) delivery of the intervention to those providers by a respected colleague. Recent research supports the delivery of information by colleagues. Hay et al., (2008) in a study of 39 physicians found that they prefer their own experience and the experience of their colleagues over evidence based medicine literature when making clinical decisions.

Avidor and colleagues' (2007) study focused on referral patterns for bariatric surgery and asked 478 physicians what would need to happen to increase their referral rates. The physicians, who had an average of 11 years of post-residency practice, responded that educating patients, physicians and nurses would be the most effective way to increase referrals to bariatric surgeons. Fifty-nine percent of the participant specifically wanted information on the postoperative care of bariatric patients. In addition, they ranked printed materials and CD-ROMS as the most desirable way to receive the education, continuing medical education (CME) as moderately desirable and Web-based training as the least desirable. Balduf and Farrell (2008) found that physicians reported a statistically significant increase in referrals if they had attended CME on bariatric surgery and had knowledge of the NHLBI treatment guidelines.

While the Avidor et al. study described what providers believed would be most effective, there is actually limited research on which interventions are most effective in increasing adherence to obesity treatment guidelines. A Cochrane Database Systematic Review titled *Improving health professionals' management and the organization of care for overweight and obese people* found that there was insufficient research on to how to improve obesity management. They did find that reminder systems, brief training interventions, shared care, in-patient care and dietitian-led treatments warranted additional research as possible interventions

66.

### **Synthesis of Literature across All Topics**

Conventional weight loss strategies have been ineffective for a majority of over weight or obese Americans. There is limited research on provider's attitudes and referrals to bariatric surgeons. The research that has been done has been completed on physicians. Physicians have been remiss in following clinical practice guidelines on the evaluation, identification and

treatment of obesity. Specifically, their knowledge of and attitude toward bariatric surgery is poor. Bariatric surgery is effective and safe as a treatment for morbid obesity, yet despite record high levels of obesity, bariatric surgery use is still low compared to the population who qualifies for this treatment. Of the patients who are seen by a bariatric surgeon for consultation, most are self-referred. There are numerous health care disparities among the population of patients seen by bariatric surgeons. Health care providers desire additional information on bariatric surgery and research shows that this will likely increase their referral of morbidly obese patients to bariatric surgeons. A multi-modal approach to provider education has been shown to be the most effective.

### **Methodology and Results**

The investigators completed training required by the University of Maryland, Baltimore including the Collaborative Institutional Training Initiative (CITI) modules, Health Insurance Portability and Accountability Act (HIPAA) training, and a program on the protection of human subjects. Institutional Review Board (IRB) approval was obtained from both GBMC (Appendix A) and the University of Maryland School of Nursing and the School of Medicine (Appendix B).

The first phase of this project included a site visit and assessment to become more familiar with GBMC routines and practices. The investigator spent 60 hours in the COMP with members of the team. Time was spent in patient visits with the bariatric surgeons, nurse practitioner and dietician. Three bariatric surgery cases were observed. Support groups and information sessions were attended. Face-to-face time was spent with the practice manager and office staff. A variety of concerns regarding bariatric surgery clinical practice such as education for post bariatric surgery patients, urinary tract infection after bariatric surgery, and referrals to bariatric surgery were discussed. The problem of low referral rates to bariatric surgeons was frequently discussed. A mechanism is in place for GBMA practices to enter their referrals into

their electronic medical record system, Meditech. Referral tracking reports are issued monthly allowing providers to analyze their impact on other providers or hospital departments, as well as investigate the impact of other providers on their service line. Total monthly referral numbers are available. A preliminary review of these data shows that there are low referrals from GBMA providers to the GBMC COMP. In addition, patients are surveyed at the COMP's monthly information sessions. COMP staff indicates that approximately 20% of the patients attending the sessions are referred by a physician. A literature review was performed on the topic as outlined earlier. The problem was found to be pervasive nationally.

The second phase of the project was development of the program. The program was designed to educate providers on the best evidence for identification, evaluation and treatment of obesity. To meet the best practice for educating this population, a variety of resources were used over the course of one year to develop the program. A detailed review of the literature, mentorship from subject matter experts, mentorship from organizational stakeholders, CPGs and teaching and evaluation principles were used to guide the program development. The program was designed to be reproducible and consisted of verbal education, clinical reminder tools, and printed materials. The list of potential items for the educational program was compiled in a survey. A convenience sample of experienced primary care providers was recruited by email from an existing database of primary care providers with the goal of achieving responses from ten primary care providers (four physicians, four nurse practitioners and two physician's assistants). The minimum number of participants of ten was selected to exceed the minimum recommended number of participants suggested for content validity evaluation<sup>67</sup>. The survey (Appendix C) was sent out to a total of sixty primary care providers (eighteen physicians, thirty-eight nurse practitioners and four physician's assistants) to achieve the minimum yield of responses. Five physicians, eight nurse practitioners and three physician's assistants responded

to the survey. The providers were given 10 days to respond to the internet survey and were asked to select which of the items would improve their ability to diagnose, evaluate and treat obese patients. SurveyMonkey was used to collect feedback from the providers. No identifiers were collected. Initial plans were made to include content in the program if 90% of the providers agreed on its inclusion. Zero percent of the items met 90% agreement. A more detailed review of content validity determined that a majority is considered sufficient for content validity, while the higher the percentage of agreement the more valid it becomes<sup>68</sup>. The inclusion criterion for the program was, therefore, modified to include items that the majority of the panel agreed upon.

Table 4 describes the responses from the primary care provider panel. Of the eleven items sent to the panel of primary care providers, six items met the inclusion criteria of greater than 50%. The items included in the program were a copy of the obesity clinical practice guidelines, handouts to give to patients with their BMI on it, handouts to give patients listing treatment options for obesity, bariatric surgery referral process information, bariatric surgery insurance reimbursement information, and a list of local bariatric surgeons. The items were ordered through the National Institutes of Health or were designed by the investigator. Designed materials were assessed for readability and adapted to the eighth grade reading level or lower and formatted in a minimum of 14 point font for decreased visual acuity<sup>69</sup>. The items were discussed with members of the GBMC COMP center. Copies of the clinical practice guidelines can be found at [http://www.nhlbi.nih.gov/guidelines/obesity/prctgd\\_c.pdf](http://www.nhlbi.nih.gov/guidelines/obesity/prctgd_c.pdf)<sup>1</sup>. The handout to give to patients listing treatment options for obesity can be found at [http://www.nhlbi.nih.gov/health/prof/heart/obesity/aim\\_kit/healthy\\_wt\\_facts.pdf](http://www.nhlbi.nih.gov/health/prof/heart/obesity/aim_kit/healthy_wt_facts.pdf)<sup>70</sup>. The handouts to give patients with their BMI, bariatric surgery referral process information, bariatric surgery insurance reimbursement information, and a list of local bariatric surgeons are appendices D, E, F and G, respectively.

In the third phase of the project, participants were recruited to attend the program. The investigator attended two GBMA practice manager meetings. Presentations about the upcoming project were presented at both meetings. During the 1<sup>st</sup> meeting the names, phone numbers and email addresses of the practice managers of 15 GBMA internal medicine, primary care, and family practice and gynecology practices were collected. Practice managers were contacted to obtain the numbers of providers in each practice. There were 90 providers total, 52 of which belonged to one practice of internal medicine attending physicians and residents. During the second meeting, contact information was verified. Seven of the 15 practices had a change in practice manager over the course of 4 months. The new practice managers were contacted and asked to select a date in the upcoming four weeks for the program to be scheduled in their office. Two of 15 practice managers responded to the first email. Subsequent emails were sent to the remaining practice managers. A total of ten practice managers responded. Eight of the ten practice managers declined to set up a session within the pilot time frame stating reasons of: 1) the providers in the practice were not interested in scheduling the program due to sufficient knowledge of obesity and its treatment, 2) the providers had recently attended or were already planning to attend an obesity program, 3) the providers schedules were too full or 4) the providers were on vacation. Practice managers who scheduled sessions were asked to send an email to all providers in their practices alerting them of the scheduled program. An advertisement (Appendix H) was also posted in the lunch room or lounge of each practice listing the date and time of the scheduled program.

The program was piloted in two practices. Of the 9 providers in these practices, 7 providers attended. The educational program was delivered individually to the providers to accommodate their patient schedule and was less than 30 minutes in length. The providers who

participated in the program were asked to complete a paper survey evaluating the program. The survey (Appendix I) was adapted from previously validated program evaluation tools.

Table 5 describes the responses from the program participants. 100 % of the providers felt that the program would improve how they cared for their obese patients. 85.7% of the providers felt that the program improved their opinion of bariatric surgery. 100% of the providers believed that because of the program they were more likely to adhere to the clinical practice guidelines for diagnosis of obesity. 100% of the providers believed that because of the program they were more likely to adhere to the clinical practice guidelines for evaluation of obesity. 100% of the providers believed that because of the program they were more likely to adhere to the clinical practice guidelines for treatment of obesity. 100 % of the participants felt that because of the program they were more likely to refer their obese patients to a bariatric surgeon.

During the sessions, providers also candidly spoke about their struggles and successes treating obese patients. Several reported having sent patients to bariatric surgery and one discussed dismay about a patient who died prior to getting bariatric surgery. Another provider requested information for the office staff on the importance of measuring BMI and also requested BMI charts for the office, indicating that BMI was not routinely documented in their practice by medical assistants. In addition, providers had questions about upcoming revisions to the clinical practice guidelines, research in pharmacotherapy, and bariatric surgery techniques.

### **Discussion**

Literature suggests that providers have suboptimal knowledge about obesity and bariatric surgery and that they are interested in learning.<sup>4, 5, 7, 9, 10</sup> In addition, they felt that education would improve referral rates to bariatric surgeons. The project yielded several pieces of information and insight regarding the care of obese patients. Foremost, while obesity is current

believed to be the largest epidemic facing our nation, only 16 out of 60 primary care providers responded to the call for panel participation. The investigator originally postulated that the panel would likely select most, if not all, of the items in the list, but this was not the case. Five of the eleven items were not selected. The panel consisted of experienced primary care providers, but their prior level of knowledge regarding obesity diagnosis, treatment and evaluation is unknown. Perhaps, the low number of selected items is related to a lack of knowledge about what they need to know to treat their patients properly. Or, in converse, it could be related to a higher level of knowledge about the subject and their lack of need for additional information. In retrospect, having the providers substantiate why they didn't select items would have been helpful. Future research might consider measuring the items that a bariatric specialist would select against those a primary care provider would select. In addition, future panels may benefit from having a visual of the items rather than only a list.

The low response rate from GBMA practice managers is also a phenomenon to examine. The investigator elected to go through the practice managers to set up the sessions so that they could be provided on-site at the practices for the convenience of the providers. In addition, the practice managers meet on a monthly basis and are easy to access. The low response rate may be due to the overburdened workload in primary care offices. It is possible that they did not have time to set up the sessions. It is also possible that they believe that their providers do not have time or that their providers are not interested. Or, could it be due to their own beliefs or negative attitudes toward obesity and bariatric surgery? Going through the practice managers may have added an unnecessary additional person and limited access to the GBMA providers. Soliciting providers in another way may have increased access to them. Future efforts at educating primary care providers should consider avoiding the added step of practice managers or using a combined approach, contacting the providers and the practice managers. Setting up

sessions in the medical staff lounge or impromptu visits at lunch time may increase the likelihood of providing the information. The large turnover in practice managers during this time may have also been influential. Organizations seeking to improve quality of care may also consider mandatory physician training in this area.

The GBMA providers that did attend the sessions were active participants in the program. The providers were engaged and receptive to the information provided. All of the participants felt the program would improve how they cared for their obese patients and believed that because of the program they were more likely to adhere to the clinical practice guidelines for diagnosis, evaluation and treatment of obesity. Six of seven participants felt that the program improved their opinion of bariatric surgery. Whether the participants had a prior positive or negative opinion of bariatric surgery is unknown. In addition, all of the participants felt that because of the program they were more likely to refer their obese patients to a bariatric surgeon.

Although the main aim of this project was to develop a program to deliver to primary care providers, a great deal of information was collected that will help form, improve and deliver future education on this subject. While the program consisted primarily of written tools that the panel request and an explanation of those tools, participants had several questions and requests. This may suggest that a tailored approach may be beneficial. In addition, dealing directly with the providers may serve more fruitful than trying to coordinate education through their office staff.

### **Plans for Translation**

While much of the research that has been completed has discussed the failure of primary care providers to adequately diagnose, manage and treat obesity, the needs of primary care providers to complete this task is not well discussed. Based on the findings of this project, a brief reproducible program including copies of clinical practice guidelines, handouts to give

patients telling them their BMI, handouts to give patients on treatment options, information on the bariatric surgery referral process, bariatric surgery reimbursement and a list of bariatric surgeons was developed. This program could easily be reproduced in other areas and would improve patient care in the obese population. Dissemination of this information to the primary care community is important, particularly among practice managers and those interested in quality improvement.

Sessions have been scheduled with nine additional GBMA practices that were unable to schedule sessions in the pilot window. Further data will be collected at those sessions and will be used to guide further educational program development. While data suggests that providers believe the program will improve their care of obese patients and increase their appropriate referrals to bariatric surgeons, future research is needed to determine if a program of this nature does, in fact, deliver this outcome.





Table 1

*Classification of Obesity*

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NIH Classification	BMI (kg/m <sup>2</sup> )
Underweight	<18.5
Normal weight	18.5 - 24.9
Overweight	25.0 - 29.9
Obesity (Class 1)	30.0 - 34.9
Obesity (Class 2)	35.0 - 39.9
Extreme Obesity (Class 3)	> 40.0

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Table 2

*Comparison of articles surveying provider attitudes regarding bariatric surgery*

Authors	Date	Survey Type/ Sampling Methods	Sample Size	Response rate	Respondents	Reliability or Validity of the questionnaire	Sample size calculated/power
Avidor, Y.; Still, C.D.; Brunner, M.; Buchwald, J.N.; Buchwald, H.	2007	Questionnaire, handed-in; all physicians in 6 specialty areas at their national meetings	NS	NS	478 (questionnaire 1) 484 (questionnaire 2)	Validated by independent testing agency	NS
Balduf, L. & Farrell, T.	2007	Cross-sectional questionnaire, mailed; random sample of family practitioners and internists from the North Caroline Health Professions Data System	611	47%	288	Content validity assessed by several experienced general surgeons	NS
Foster, G.; Wadden, T.; Makris, A.; Davidson, D.; Sanderson, R.; Allison, D.; Kessler, A.	2003	Questionnaire, mailed; random sample of family physicians in 2 geographical areas from AMA	5000	13%	600	NS	NS

NS (not specified)

Table 2 Continued

*Comparison of articles surveying provider attitudes regarding bariatric surgery*

Authors	Date	Survey Type/ Sampling Methods	Sample Size	Response rate	Respondents	Reliability or Validity of the questionnaire	Sample size calculated/power
Perlman, S.E.; Reinhold, R.B.; Nadzam, G.S.	2007	Questionnaire, mailed; all family physicians in Connecticut	620	21%	129	NS	NS
Sansone, R.A.; McDonald, S.; Wiederman, M.W.; Ferreira, K.	2007	Cross-sectional questionnaire, mailed; all members of internal medicine, family medicine and obstetrics/gynecology medical staff of a mid-sized, mid-west, suburban, community hospital	246	40%	99	NS	NS
Schuster, R.; Morton, J.M.; Liu, G.Y.; Alami, R.S.; Curet, M.J.	2006	Questionnaire, handed-in; all medical students interviewing for surgical residency	61	93%	57	NS	NS
Thuan, J-F. & Avignon, A.	2005	Cross-sectional questionnaire, mailed; all general practitioners in one French region	744	82%	607	NS	NS

NS (not specified)

Table 3  
*Findings of articles surveying provider attitudes toward bariatric surgery*

Author	Year	Would refer patients meeting criteria to a bariatric surgeon	Ever referred patients to a bariatric surgeon	If needed, would consider having bariatric surgery	Would refer a friend or family member for bariatric surgery
Avidor, Y. et al.	2007		71%	Patient driven: 45.5%	
				Provider driven: 54.5%	
Balduf, L. & Farrell, T.	2008		76%	Patient driven: 53%	
				Provider driven: 47%	
Foster, G. et al.	2003	23%			
Perlman, S. et al.	2007		85%	63%	63%
Sansone, R. et al.	2007	84%			
Schuster, R. et al.	2006			77%	89%
Thuan, J-F. & Avignon, A.	2005				

Table 4

*Survey of Primary Care Providers*

Item	% Agreement
	N=16
A copy of the obesity clinical practice guidelines	68.8
Laminated BMI charts	50
Handouts for you to give to your patients with their BMI on it	56.3
Handouts for you to give to your office staff on the importance of documenting BMI	18.8
Posters for your waiting room instructing patients to ask you about their BMI	18.8
Posters for your exam room instructing patients to discuss their BMI with you	18.8
Obesity presentation	43.8
Handouts for you to give your patients listing treatment options for obesity	81.3
Bariatric surgery referral process information	56.3
Bariatric surgery insurance reimbursement information	56.3
List of local bariatric surgeons	56.3

Table 5

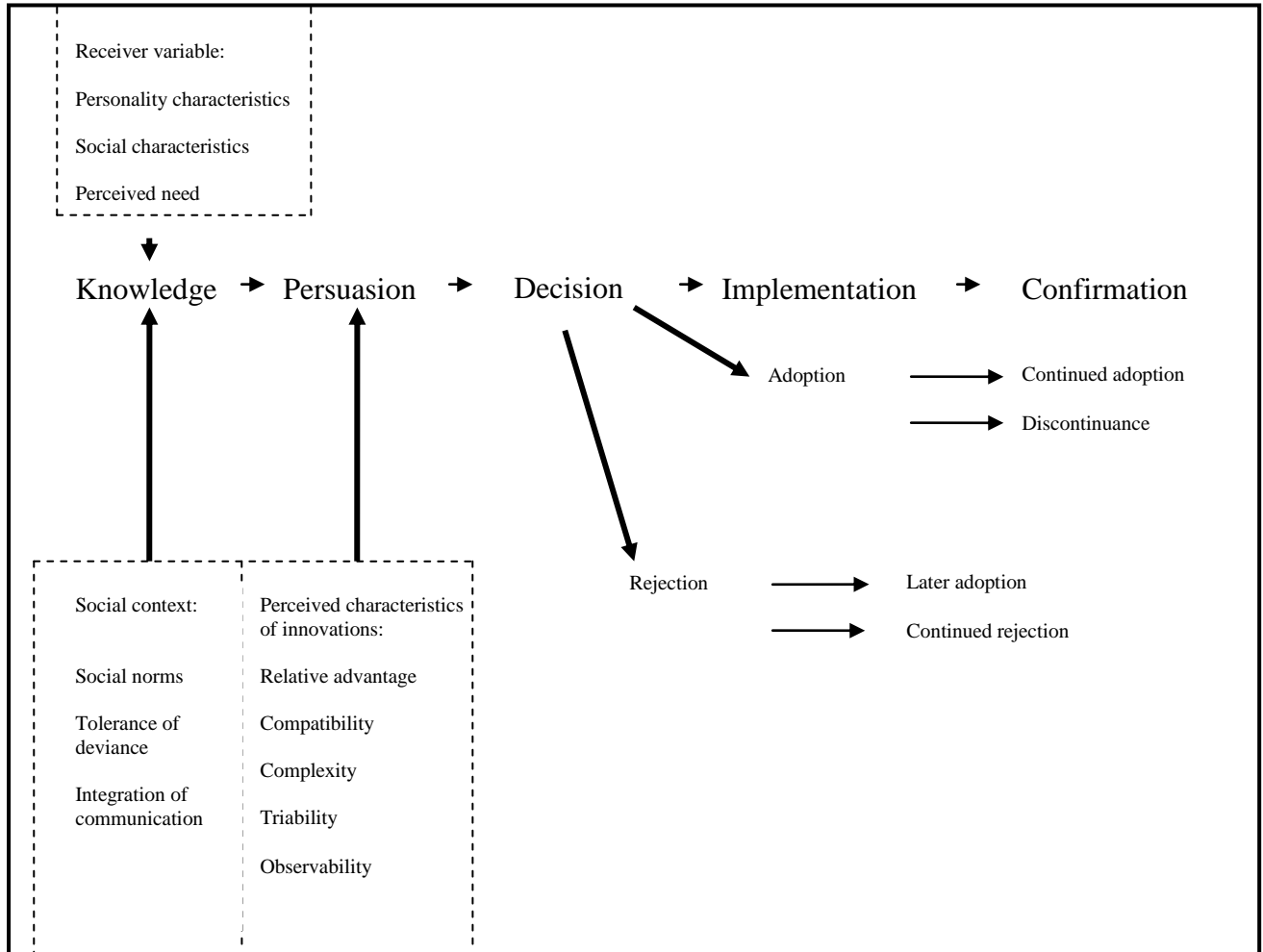
*Survey of Program Participants*


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Item	% Agreement
	N=7
<hr/>	
This program will improve how I care for my obese patients.	100
This program improved my opinion of bariatric surgery.	85.7
Because of this program I am more likely to adhere to the clinical practice guidelines for diagnosis of obesity.	100
Because of this program I am more likely to adhere to the clinical practice guidelines for evaluation of obesity.	100
Because of this program I am more likely to adhere to the clinical practice guidelines for treatment of obesity.	100
Because of this program I am more likely to refer appropriate patients to a bariatric surgeon.	100

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Figure 1: Diffusion of Innovations



Appendix A: GBMC IRB approval



INSTITUTIONAL REVIEW BOARD

IRB Office: 443-849-2379  
Voice Mail: 443-849-3120  
Fax: 443-849-3776  
[www.gbmc.org/education/irb](http://www.gbmc.org/education/irb)

*EXPEDITED REVIEW for EXEMPTION*

March 15, 2010

Shannon Reedy, MS, CRNP  
12002 Cedar Lane  
Kingsville, Maryland MD 21087

**RE: A Program to Increase Bariatric Surgery Referrals through Clinical Practice Guidelines**  
GBMC Study Coordinator: Kate Reinhardt  
Assigned IRB #10-014-03  
*New Protocol for Exemption*

Dear Ms Reedy:

On behalf of the Institutional Review Board of the Greater Baltimore Medical Center on **March 15, 2010** I reviewed your Application and protocol submission for initial IRB Review. The purpose of your project is to develop a program for primary providers to familiarize them with current clinical practice guidelines for the identification, evaluation and treatment of obesity, thereby increasing adherence to the obesity clinical practice guidelines and referrals to the Comprehensive Obesity Management Program

Your submission also included an advertisement for participants, two signed Conflict of Interest statements, Dear Provider letter, a survey form, and a Fee Waiver request form.

Approval has been granted for you to conduct this research project at GBMC. If there is any change in the protocol that would affect the scope or the quality of the protocol, please notify the IRB in writing.

This Expedited Review and approval will be reported to the IRB on **April 19, 2010**.

Sincerely,

James H. Mersey, MD  
Chairman, Institutional Review Board

jad

Appendix B: UMB IRB approval



University of Maryland, Baltimore  
Institutional Review Board (IRB)  
Phone: (410) 706-5037  
Fax: (410) 706-4189  
Email: [hrpo@som.umaryland.edu](mailto:hrpo@som.umaryland.edu)

Exempt Confirmed Notification

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Date: March 22, 2010

To: Joan Davenport  
From: IRB Chair/Vice Chair: Lisa Dixon  
RE: HP-00044876  
Risk designation: Minimal Risk  
Exempt Confirmed Date: March 22, 2010

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This is to certify that University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) has received and reviewed correspondence regarding the above referenced protocol entitled, "A Program to Increase Bariatric Surgery Referrals Through Clinical Practice Guidelines"

Your protocol has been determined to be exempt under 45 CFR 46.101(b), from IRB review based on the following category(ies):

45 CFR 46.101(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Investigators are reminded that the IRB must be notified of any changes in the study. In addition, the PI is responsible for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(4)(iii)).

- Research activity involving veterans or the Baltimore VA Maryland Healthcare System (BVAMHCS) as a site, must also be approved by the BVAMHCS Research and Development Committee prior to initiation. Contact the VA Research Office at 410-605-7131 for assistance.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.

Appendix C: Survey to Primary Care Providers:

Dear Provider,

As a student in the Doctor of Nursing Practice program at the University of Maryland Baltimore, I am developing a program for primary care providers on the best evidence for identification, evaluation and treatment of obesity. The program will be reproducible and may consist of a verbal educational program, presentation of clinical reminder tools and review of printed materials. To ensure that the content of the program meets the needs of practicing primary care providers, I am asking for your assistance.

I am asking you to be a member of a panel of primary care providers that will review a list of potential content for the program. A minimum of ten primary care providers (four physicians, four nurse practitioners and two physician's assistants) will be included as panel members.

The following URL provides access to a questionnaire on content to be included in the program. The questionnaire is anonymous and no identifiers will be collected. Job status will be collected to ensure the minimum number in each provider category is met. This URL will be open until midnight on \_\_\_\_\_: <http://www.surveymonkey.com/s/BLQF257>. After I have received feedback from the panel, I will develop the program and deliver it to primary care providers in the community.

Thank you, in advance, for your participation,

Shannon Reedy, MS, CRNP

Appendix C: Survey to Primary Care Providers cont.:

You have been invited to participate in this survey because you are a physician, nurse practitioner or physician’s assistant who works in primary care, internal medicine, family practice or gynecology. The goal of the program is to increase use of obesity clinical practice guidelines by primary care providers. By completing this survey, your responses will be used to evaluate the content of a planned educational program. No identifiers will be collected. Your responses will not be linked to you. You do not need to participate, and there will be no penalty for not participating. The survey will take you less than 15 minutes.

I am a: Physician  
Nurse practitioner  
Physicians assistant

Please indicate which of the following would improve your ability to diagnose, evaluate and treat obese patients. You may select all, some or none of them.

	A copy of the obesity clinical practice guidelines: <i>The Practical Guide: Identification, Evaluation and Treatment of Overweight and Obesity in Adults</i>	
	Laminated BMI charts	
	Handouts for you to give to you patients with their BMI on it	
	Handouts for you to give to your office staff on the importance of documenting BMI	
	Posters for your waiting room instructing patients to ask you about their BMI	
	Posters for your exam room instructing patients to discuss their BMI with you	
	Obesity presentation with specifics about:	surgical criteria success rate failure/complication rate patient beliefs and vignettes process for referrals post-surgery follow-up
	Handouts for you to give your patients listing treatment options for obesity	
	Bariatric surgery referral process information	
	Bariatric surgery insurance reimbursement information	
	List of local bariatric surgeons	

Appendix D: Handout to patients with BMI

## Body Mass Index



Body mass index (BMI) is a measure of body fat based on height and weight. It applies to both adult men and women. It also lets you compare yourself against what is considered a healthy weight.

To estimate your BMI, use the table on the back of this page. First find your height in the nearest inches in the column on the left, then move across the row to find the number closest to your weight in pounds. The number at the top of that column is your estimated BMI.



Your BMI today is:

\_\_\_\_\_

What does that mean?

Less than 18.5	underweight
18.5 to 24.9	normal weight
25 to 29.9	overweight
30 or more	obese
greater than 35	very obese

Schedule a follow-up appointment to discuss your BMI

Appendix E: Bariatric surgery referral process

## GBMC Comprehensive Obesity Management Program



**Congratulations! By looking into weight loss surgery you have taken the first step on your journey to health. The information below will help you with the next steps:**

### 1. Register for an Information Session

All patients must attend an information session before scheduling an appointment with our surgeons. Information sessions are held on select Wednesdays from 5:30 - 7:00 pm. Register for a session online or call us at 443-849-3779.

### 2. Determine Your Body Mass Index (BMI)

BMI is a measure of body fat based on height and weight. It applies to both adult men and women. To calculate your BMI, talk to your primary care provider or visit [http://www.asbs.org/Newsite07/patients/asbs\\_bmi.htm](http://www.asbs.org/Newsite07/patients/asbs_bmi.htm)

	Obesity Class	BMI (Kg/m <sup>2</sup> )
<b>Overweight</b>		25 - 29.9
<b>Obese</b>	I	30 - 34.9
<b>Obese</b>	II	35 - 39.9
<b>Morbid Obesity</b>	III	> 40

### 3. Understand the Guidelines

Weight loss surgery should be considered for patients with a BMI of 40 or more. It should also be considered for patients with a BMI of 35 or more and other health problems related to obesity such as sleep apnea and diabetes. If you decide that weight loss surgery is right for you, it is important that you understand the guidelines set by your insurance company and our program. Patients should contact their insurance company and/or human resource office to obtain specific guidelines and approval for weight loss surgery.

Appendix E: Bariatric surgery referral process cont.

**4. Prepare for Information Session**

Before your information session, complete a patient history and a patient registration form. The forms can be found at <http://www.gbmc.org/body.cfm?id=486>.

Please hand in these forms along with the following at the sign-in desk before the start of the session.

- A copy of the front and back of your insurance card
- Copies of paper work from weight loss attempts within the past two years

**5. Wait to Hear from the Program Staff**

Once you have attended an information session, one of our staff members will:

- Review your paper work
- Look to see if you meet the criteria to have weight loss surgery
- Check on your benefits with your insurance company
- Call you to schedule an appointment

**6. Attend Your Appointment**

Bring with you to your first appointment:

- A current driver's license or photo ID
- Results of any lab or tests performed within the last 6 months
- A referral from you Primary Care Provider if required by your insurance company
- All surgical and operative records from prior bariatric surgeries

At your first appointment, patients will meet with:

- A financial coordinator to review your insurance policy and financial obligations
- A dietitian to review weight loss and diet history as well as obtain a diet plan
- A nurse practitioner to review your medical history
- A surgeon to discuss your surgical weight loss options and plan your program

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GBMC  
Comprehensive Obesity Management Program  
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Appendix F: Bariatric surgery insurance information

**Bariatric Surgery Insurance Information**

Under COMAR 31.10.33.03 and 31.11.06, all insurance companies in the State of Maryland are mandated to cover bariatric surgery unless they are self-funded. While there are many Marylanders who are insured under self-funded plans, many of them still elect to cover bariatric surgery.

In addition, where coverage is mandated, only the following restrictions can be placed on the insured. They may be less restrictive, but not more:

- 18 years or older
- BMI of 40 or above OR BMI equal to or greater than 35 with one or more of the following co-morbid conditions <sup>1</sup>
- Completion of structured diet program<sup>2</sup>
- Psychological fitness evaluation for bariatric surgery

Medicare covers bariatric surgery at 80%

Medicaid covers bariatric surgery at 100%

The type of surgery covered is not mandated, but nearly all insurance companies cover gastric bypass or gastric banding.

All patients should check with their insurance provider about coverage specifics.

<sup>1</sup> Hypertension, cardiopulmonary condition, sleep apnea, diabetes or any life threatening or serious medical condition that is weight induced

<sup>2</sup>In the 2-year period that immediately precedes the request for the surgical treatment of morbid obesity: (i) One structured diet program for 6 consecutive months; or (ii) Two structured diet programs for 3 consecutive months.

## Appendix G: Local bariatric surgeons

## Baltimore Bariatric Surgeons

<b>Doctor</b>	<b>Area</b>	<b>Phone #</b>	<b>Affiliation</b>
<b>Peter Liao</b> <b>Babak Moeinolmolki</b>	Towson	(443) 849-3779	GBMC Comprehensive Obesity Management Program
<b>David von Rueden</b>	Catonsville	(410) 368-3003	St. Agnes Hospital St. Joseph's Hospital
<b>Andrew Averbach</b>	Catonsville	(410) 368-8725	St. Agnes Hospital
<b>Kuldeep Singh</b>	Fulton	(301) 490-2913	St. Agnes Hospital
<b>Thomas Magnuson</b> <b>Michael Schweitzer</b> <b>Anne Lidor</b> <b>Kimberley Steele</b> <b>Hien Nguyen</b> <b>Michele Shermak</b>	Baltimore	(410) 550-0409	The Johns Hopkins Center for Bariatric Surgery
<b>Terrence Fullum</b> <b>Stephen McKenna</b> <b>Sung Kim</b>	Havre de Grace	(443) 843-6360	Upper Chesapeake Bariatrics
<b>Apparao Vanguri</b>	Baltimore	(410) 529-7500	Bariatric Institute at Franklin Square
<b>Mark Kligman</b> <b>Emanuele Lo Menzo</b> <b>Steven Scharf</b> <b>Ronald Silverman</b>	Baltimore	(410) 328-8940	University of Maryland Center for Weight Management and Wellness
<b>Alex Gandsas</b> <b>Christina Li</b>	Baltimore	(410) 601-4486	Sinai Hospital
<b>William Roe, Jr.</b>	Towson	(410) 583-0123	Baltimore Bariatrics

Appendix H: Program Advertisement:

## A Program to Increase Bariatric Surgery Referrals through Clinical Practice Guidelines

Physicians, nurse practitioners and physician's assistants who work for Greater Baltimore Medical Associates in primary care, internal medicine, family practice or gynecology are invited to attend an obesity and bariatric surgery program. The program is designed to increase adherence to clinical practice guidelines for the diagnosis, evaluation, and management of obesity and increase appropriate referrals to the Comprehensive Obesity Management Program at Greater Baltimore Medical Center.

Participants will be provided tools to help guided them in the diagnosis, evaluation, and management of obesity including determining appropriate patients to refer to a bariatric surgeon.

Participation is voluntary and will involve attending a 30 minute program that will be held the providers office practice. Participants will be asked to complete a survey at the end of the program to evaluate the program. No identifiers will be collected. Your responses will not be linked to you. You do not need to participate, and there will be no penalty for not participating. The survey will take you less than 15 minutes.

If you are interested in participating, or would like more information, please contact Shannon Reedy, at telephone number: 410-706-8129, or e-mail: [reedy@son.umaryland.edu](mailto:reedy@son.umaryland.edu)

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Appendix I: Survey to Participants

You have been invited to participate in this survey because you are a physician, nurse practitioner or physician’s assistant who works for Greater Baltimore Medical Associates in primary care, internal medicine, family practice or gynecology and attended an obesity and bariatric surgery program. The goal of the program is to increase use of obesity clinical practice guidelines by primary care providers. By completing this survey, your responses will be used to evaluate the educational program. No identifiers will be collected. Your responses will not be linked to you. You do not need to participate, and there will be no penalty for not participating. The survey will take you less than 15 minutes.

Evaluation – Please circle the response which most closely represents your view on each of the following.

This program will improve how I care for my obese patients.	YES	NO
This program improved my opinion of bariatric surgery.	YES	NO
Because of this program I am more likely to adhere to the clinical practice guidelines for diagnosis of obesity.	YES	NO
Because of this program I am more likely to adhere to the clinical practice guidelines for evaluation of obesity.	YES	NO
Because of this program I am more likely to adhere to the clinical practice guidelines for treatment of obesity.	YES	NO
Because of this program I am more likely to refer appropriate patients to a bariatric surgeon.	YES	NO

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