Finally, for the millions of Americans who have spent $33 billion on weight-loss products that have proven to be inadequate, in February 2007, the FDA approved a weight-loss medication for over-the-counter use. This industry breakthrough enables obese individuals to make the decision to purchase an approved diet pill without a prescription.

Orlistat (marketed under the brand name, Alli™) is a capsule which works in the intestinal system to inhibit the absorption of a portion of the fat that we eat. Orlistat made its debut on the weight-loss market scene in 1999 as Xenical®, a prescription medication which has twice as much of the active ingredient as Alli™. Scientists subsequently discovered that a lower dose could produce similar degrees of weight-loss with fewer adverse side effects — and thus Alli™ was born. Though many patients have anxiously awaited Orlistat’s emergence on the market, it is imperative that they be wise consumers and understand the risks and benefits of any weight-loss program — including Alli™.

**What is Alli™?**

Alli™ is marketed as a “diet plan” that encourages users to initiate a lifestyle that includes a balanced, reduced-calorie diet with an average of 15 grams of fat per meal, and regular physical activity before starting the capsules. With these lifestyle modifications alone, obese patients (defined as those with BMI greater than 30kg/m²) can expect to lose a modest amount of weight as long as these changes become a permanent part of one’s life.

**How much weight will I lose with Alli™?**

By minimizing the fat absorbed from the gut, one 60 mg Orlistat capsule three times a day is expected to increase weight-loss by 50 percent compared with dieting alone. For example, a woman who is 5’6” who weighs 167 lbs. and gets down to 157 lbs. with dieting can expect to reach a weight of 152 lbs. if the Alli™ plan is adopted. This 15 lb. weight-loss could be effective in improving this patient’s overall health and quality of life.

**Where can I purchase Alli™?**

One of the most attractive features of Alli™ is its availability — it can be purchased online and in major pharmacies and grocery stores. Though

*Alli™ continued on page 14*
A Message from OAC Chairman, Jim Fivecoat

This year the Obesity Action Coalition (OAC) and the American Society for Metabolic and Bariatric Surgery (ASMBS) Foundation had the excellent opportunity to jointly host the annual “Walk from Obesity.” This year’s slogan for the Walk was, “Partnering to improve the lives of all those affected by obesity through education, research and advocacy.” And, that is exactly what the Walk is all about for those affected by the disease of obesity. This year’s Walk, the largest gathering of patients, gave us the representation needed to raise our voices and bring obesity to the forefront of the healthcare community.

I would like to take a moment and thank all the volunteers, ASMBS Foundation staff, OAC staff and many others who helped organize the Walk and participated in the 2007 “Walk from Obesity.” In addition, I would like to thank the 2007 “Walk from Obesity” National sponsors for your generous support of this important event. This year’s sponsors include: Platinum Sponsors: Covidien; and Ethicon Endo-Surgery; Gold Sponsor: Allergan; Bronze Sponsors: Bariatric Advantage; ON-Q PainBuster; and JourneyLite.

I was fortunate enough to be able to join with the Cleveland, OH Walk while attending and speaking at the Cleveland Clinic’s Obesity Summit. It is exciting to hear about the work being done studying the need to combine therapies, the complexity around the causes of obesity and the new innovations taking place in the industry supporting the treatment of obesity.

We look forward to next year’s Walk and hope to once again “Raise the Voice” of all those affected by the disease of obesity, morbid obesity and childhood obesity.

In this issue of OAC News, we address topics such as, the popular diet drug Alli™, the gastric sleeve surgery, affordable healthy foods for children and families and much more. In addition, be sure to check out the “Advocacy” section where we discuss the issues with Medicare and local coverage determinations.

As always, we strive to provide you, the reader, with the most up-to-date information in the obesity community and latest news from the OAC. If there are any topics that you would like to see addressed in future issues of OAC News, please email them to info@obesityaction.org and we will be sure to consider them.

Thank You!
Gallbladder disease is one of the most common surgical conditions seen in our society. Since it reportedly affects 12 percent of adults, everyone probably knows someone that has had their gallbladder removed. The surgery to treat gallbladder disease by removal of the gallbladder is known as a cholecystectomy.

With more than a half million operations performed each year, the cholecystectomy is one of the most common surgeries performed today. Although there are many risk factors which would increase the likelihood of developing gallbladder disease, two of the major causes are obesity and rapid weight-loss; therefore, gallbladder disease is an important issue for an obese patient.

The information provided in this article is intended to allow patients the ability to appropriately consider all of the available treatment options for gallbladder disease, since they are among the highest at risk within the population.

Detection of Gallbladder Disease

Gallbladder disease is indicated by the presence of gallstones, which can be detected with an ultrasound. However, the mere presence of gallstones does not normally require surgical treatment, as long as the gallstones are asymptomatic. Two-thirds of all patients who develop gallstones remain asymptomatic and thus do not require surgical treatment.

The most common symptom of gallstones is periodic pain that occurs when gallstones block the outlet of the gallbladder. This recurring pain represents the classic “gallbladder attack.” The pain is felt just under the breastbone in an area called the epigastrium, commonly referred to as the “pit” of the stomach. The pain will also often move to the back, and can be accompanied by nausea and occasional vomiting.

“Gallbladder attacks” usually last no more than a few hours before the pain spontaneously resolves. If the pain only slightly subsides for a moment before increasing and settling to just below the right rib cage, an infection in the gallbladder could be developing. This complication of gallbladder disease is known as cholecystitis.

To prevent cholecystitis and other complications of gallbladder disease, early and prompt removal of the gallbladder is recommended as soon as symptoms develop. Development of symptoms indicates progressive active gallbladder disease and the need to consider surgery.

Causes and Treatments for Gallbladder Disease

As previously mentioned, one of the major causes among the many risk factors for gallbladder disease is obesity; therefore, many patients have already had their gallbladders removed prior to their treatment for their obesity. However, patients that have not previously undergone a cholecystectomy may develop symptomatic gallstones after a period of rapid weight-loss (i.e. bariatric surgery).

Studies suggest that a patient undergoing weight-loss surgery can have as high as a 25-30 percent risk of developing symptomatic gallstone disease within the first year after their bariatric procedure; therefore, some physicians suggest the routine removal of the gallbladder for all patients undergoing weight loss surgery. This practice of routine removal of the gallbladder has raised debate among physicians. Different physicians practice different philosophies regarding surgery and treatment options.

Despite the statistics showing that up to 30 percent of bariatric patients will need their gallbladders surgically removed during the rapid weight-loss phase after their operation, the issue of risk versus benefit needs to be properly included in the decision making process. The flip side of the argument, in routine practice of removing the gallbladder, 70-75 percent of bariatric patients will have their gallbladder removed unnecessarily. This subjects the vast majority of patients to unnecessary risk.

Risks of Gallbladder Surgery

Since having a cholecystectomy is so common in society, the fact that it is a major surgery with major complications is often forgotten and replaced by the thought of being a routine minor surgery with minimal risks. Cholecystectomy is a major operation and has its own set of major associated complications. The most concerning complication of a cholecystectomy is an injury to the main bile duct.

The main bile duct is the passageway for bile to move from the liver to the duodenum, which is the first portion of the small
Snacking is almost a ritual in America. Everywhere you go – from the coffee shop to the gas station to your office, you are presented with convenient foods. However, most of these foods are unhealthy and high-calorie, and they are often expensive. This article looks at how to make snacking part of a healthy diet and gives you some ideas of healthy snacks for both adults and kids.

Is Snacking Healthy?

A good question to start with is should we snack at all? Many of us have grown up with the idea of “three square meals a day” as being all we need. In this model, snacks are unnecessary extras or treats. But, well-planned snacks can have a real place in a healthy diet.

Snacks can be a great way to get in extra nutrition. For children who often cannot eat a lot in one sitting, snacks can help them to get in valuable nutrients throughout the day. The same is true for anyone with limited appetite or food intake – such as those who have had weight-loss surgery or the elderly. Snacks can also be a great source of nutrition for those who are simply really busy.

Many of us who juggle family and jobs and other obligations miss out on healthy, home-cooked meals. When done right, snacks can provide nutrition to make up for the breakfast that was really just a cup of coffee or the lunch that was a handful of crackers eaten between meetings. Finally, snacks can help prevent unhealthy eating habits.

When we are hungry we tend to make poor food choices and over eat. For example, if you didn’t
Snacking can very easily become an unhealthy part of the diet. When snacking is not planned, it frequently consists of high-calorie, high-fat foods and drinks that do not contribute useful nutrition to your diet – but do contribute to weight gain.

The New Generation of Snack Foods

There is a new trend in snack foods that it is hard to miss if you have been in the grocery store recently: the 100 Calorie Pack. Mostly, these are small servings of chips, cookies and crackers. While these products do serve to provide a controlled portion of a food that you might normally eat a much larger serving of, they are almost always unhealthy foods. Additionally, if you look carefully, you will find that these products cost about twice as much as their full-calorie counterparts. Still, it is true that many of us will eat less when we are given smaller portions and more when we are given bigger portions regardless of how hungry we really are. So, if you absolutely must have those cookies – this is a safer bet than opening the whole bag.

Snack bars are also everywhere. Some are fine, but many are nothing more than candy bars with some added protein. Many are also shockingly high in calories and fat. If you and your family like this kind of snack, be sure to carefully read the labels.

A Few Words on Planning

It’s really easy to find a soda or a candy bar whenever you want one (or not!). But, healthy snacks are not always as convenient – and may not look as good sitting next to the chocolate chip cookie or potato chips. If you plan to have healthy snacks available in convenient locations, you will both be more likely to reach for them and less likely to reach for the unhealthy foods.

A good idea is to add a “snack” list to your grocery list. Include some things that can be in your refrigerator and cupboards, but also some portable items that can be in your car, in your child’s back-pack and in your desk drawer at the office.

Healthy Tip!

A better use of pre-measured snacks are the great little packets of nuts, dried fruit and whole-grain trail mixes. While many of these products are intended for kids’ lunches, they are great to toss in your purse or glove compartment for a healthy on-the-go food.

Healthy continued on page 11
As patients begin investigating surgical weight-loss options, one of the first questions to arise is “what procedure is best for me?” The answer to this question must come after thorough research regarding the risk and benefits of each procedure and an evaluation to determine the individual patient’s risk for undergoing surgery.

About 80 percent of the bariatric procedures performed in the United States are gastric bypass procedures. The other 20 percent are comprised of restrictive procedures, such as the laparoscopic adjustable gastric band. The laparoscopic sleeve gastrectomy (LSG), a relative newcomer to bariatric surgery, is growing in popularity.

The sleeve gastrectomy originated as the restrictive part of the duodenal switch operation. In the last several years, though, it has been used by some surgeons as a staging procedure prior to a gastric bypass or duodenal switch in very high risk patients. It has also been used as a primary, stand-alone procedure by some surgeons.

**How is Sleeve Gastrectomy Performed?**
The majority of sleeve gastrectomies performed today are completed laparoscopically. This involves making five or six small incisions in the abdomen and performing the procedure using a video camera (laparoscope) and long instruments that are placed through these small incisions.

During the sleeve gastrectomy, about 75 percent of the stomach is removed leaving a narrow gastric tube or “sleeve” (see picture on page 7). No intestines are removed or bypassed during the sleeve gastrectomy. This procedure takes one to two hours to complete. This short operative time is an important advantage for patients with severe heart or lung disease.

**How Does the Sleeve Gastrectomy Cause Weight-Loss?**
Sleeve gastrectomy is a restrictive procedure. It greatly reduces the size of the stomach and limits the amount of food that can be eaten at one time. It does not cause decreased absorption of nutrients or bypass the intestines. After this surgery, patients feel full after eating very small amounts of food. Sleeve gastrectomy may also cause a decrease in appetite. In addition to reducing the size of the stomach, the procedure reduces the amount of the “hunger hormone,” ghrelin, produced by the stomach. The duration of this effect is not clear yet, but most patients have significantly decreased hunger after the operation.

**Who Should Have a Sleeve Gastrectomy?**
This operation has been used successfully for many different types of bariatric patients. Since it is a relatively new procedure, there is no data regarding weight-loss, complications or weight regain beyond three years. At the Cleveland Clinic, we use this procedure as part of a staged approach for high-risk patients. Patients who have a very high body mass index (BMI) or severe heart or lung disease may benefit from a shorter, lower risk operation such as the sleeve gastrectomy as a first stage procedure. Sometimes, the decision to proceed with the sleeve gastrectomy is made in the operating room due to an excessively large liver or extensive scar tissue to the intestines that make gastric bypass impossible.

In patients who undergo LSG as a first stage procedure, the second stage (gastric bypass) is performed 12 to 18 months later after significant weight-loss has occurred, the liver has decreased in size and the risk of anesthesia is much lower. Though this approach involves two procedures, we believe it a safe and effective strategy for selected high-risk patients.

LSG is also being used as a primary weight-loss procedure in lower BMI patients. Because this is a more recent application...
of this procedure, it is currently being performed as part of an investigational protocol for this lower BMI patient group.

**How Much Weight-loss Occurs after LSG?**
Several studies have documented excellent weight-loss up to three years after LSG. In higher BMI patients who undergo LSG as a first stage procedure, the average patient will lose 40 – 50 percent of their excess weight in the first two years after the procedure. This typically equates to about 125 pounds of weight-loss for patients with a BMI greater than 60.

Patients with lower BMI’s who undergo LSG will lose a larger proportion of their excess weight (60 – 80 percent) within three years of the surgery. Weight-loss after LSG has been directly compared to Laparoscopic Adjustable Gastric Banding (LAGB). In a randomized trial comparing LSG to LAGB, LSG resulted in better weight-loss at three years (66 percent versus 48 percent excess weight-loss). Additionally, more than 75 percent of patients will have significant improvement or resolution of major obesity-related co-morbidities such as diabetes, hypertension, sleep apnea and hyperlipidemia following sleeve gastrectomy.

**What are the Risks of Sleeve Gastrectomy?**
The risk of major post-operative complications after LSG is 5-10 percent, which is less than the risk associated with gastric bypass or malabsorptive procedures such as duodenal switch. This is primarily because the small intestine is not divided and reconnected during LSG as it is during the bypass procedures. This lower risk and shorter operative time is the main reason we use it as a staging procedure for high-risk patients.

Complications that can occur after LSG include a leak from the sleeve resulting in an infection or abscess, deep venous thrombosis or pulmonary embolism, narrowing of the sleeve (striction) requiring endoscopic dilation and bleeding. Major complications requiring re-operation are uncommon after sleeve gastrectomy and occur in less than 5 percent of patients.

**Is LSG a Good Choice for Me?**
You should first know the risks and benefits of sleeve gastrectomy, adjustable gastric banding and gastric bypass. For high-risk patients and patients with very high BMI’s, we discuss LSG as a first-stage procedure prior to gastric bypass. We are also conducting a clinical trial that includes sleeve gastrectomy for lower BMI patients with diabetes. Ultimately, the decision regarding which procedure to perform is based on each patient’s operative risk and their expectations and goals for surgical weight-loss.

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*S References for this article may be found in the online version of this article in the October issue of “OAC News” located at [www.obesityaction.org](http://www.obesityaction.org).

**About the Authors:**

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Philip Schauer, MD, is past president of the American Society for Metabolic & Bariatric Surgery and is the Director of the Bariatric and Metabolic Institute at the Cleveland Clinic. He has been published extensively on bariatric procedures and outcomes and has been instrumental in promoting the field of bariatric surgery worldwide through his many leadership roles.

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**Sleeve gastrectomy may be performed for the following reasons:**

- Body Mass Index is greater than 60
- Severe comorbidities (cardiac, pulmonary, liver disease)
- Advanced age
- Inflammatory bowel disease (Crohn’s disease)
- Need to continue specific medications (anti-inflammatory medicines, transplant medications)
- Need for continued surveillance of the stomach (that couldn’t be evaluated after a gastric bypass)
- Severely enlarged liver found during the operation
- Severe adhesions (scarring) to the bowel found during the operation
- Any combination of the above that significantly increases the patient’s risk
At 5’2” and 256 pounds, running a marathon was the last thing on Alison Show’s mind. All of her life Alison had been affected by the disease of obesity. Growing up in an Eastern European home, food was always a staple in the household.

“My family always ate and the men in the family were blue-collar guys that got their exercise from working; however, the women did not exercise,” said Alison.

By first grade, Alison realized she had some weight issues. She recalled an eye-opening moment one day during ballet class. “I remember my teacher brought in my costume and I tried to put it on and it wasn’t fitting. At the time I was 185 pounds in first grade,” said Alison. You could hear in Alison’s voice that recalling this time in her life is still sobering to her.

As Alison aged through her teens and early 20s, she tried all types of weight-loss programs and gimmicks. “You name it and I tried it. I tried all the commercial weight-loss plans, pills, diets and so on. Nothing worked. The weight always came back,” said Alison.

With the failure of these programs, and the physical and emotional stress of obesity, Alison began to explore other treatment options. Having been affected by diabetes and high cholesterol, Alison wanted to take charge of her life and become healthier.

In 2002, she began to research weight-loss surgery. She talked to friends, family members and her doctor for more information on the procedure. “I took time and thought about it. My insurance completely covered it, so basically it was a decision I had to make. I decided to go with Roux-en-Y gastric bypass surgery. I contemplated the band too, but at the time, there just wasn’t a lot of information on it out there,” said Alison.
At a weight of 256 pounds, Alison had gastric bypass surgery. Today, Alison’s life is much different and well, you could say that it’s almost a different life. Before surgery, Alison was involved with the opera as a singer.

“The differences in my life post-surgery are amazing. There is such a stigma that goes with obesity. In opera, it’s always expected that the women are larger and after I had the surgery, I simply did not fit into that role anymore. I began to notice that I was offered more theater parts,” laughed Alison.

You can tell in Alison’s voice that the stigma issues associated with this disease were a big part of her life. She spoke on many issues such as the workplace, friends and family. She told me of a time when she began to lose weight and started to notice a difference in friends.

“You know, it’s funny how people treat you different after surgery. Some of my friends said I took the ‘easy way out.’ They wanted the ‘fat’ friend to be with them. I had surgery because I wanted to be healthier and change my life,” said Alison.

In the workplace, Alison also noticed a difference. The job she currently works at only knows her post-surgery and she’s experienced a completely different atmosphere after losing the weight. “It’s amazing the difference I see without the weight. Guys hold the door for you, people compliment you and stuff. It honestly makes me wonder sometimes if it’s superficial. Before all this, I just felt invisible,” laughed Alison.

Today, Alison has a new interest in her life and it’s something that she never thought she could do – marathons. In 2005, Alison entered a lottery for the New York City Marathon. “I told all my friends that I entered it, and I was like there’s no way I’ll get picked. Sure enough, I got picked,” giggled Alison.

With a New York City Marathon breathing down her neck, Alison knew she had to start training. She began training five months prior. Some days she’d run three miles, then five and then seven. Before she knew it, she was ready. Alison would train after work and also on the way to her side job as “Scooter the Cow.” More on that later.

For her first marathon, she finished with a time of five hours and 51 minutes. “I was so proud of myself. I remember thinking during the run, ‘I can’t believe I am doing this. This is amazing.’ Up next, Alison entered the 2006 New York City Marathon and finished with a time of five hours and 20 minutes – shaving more than 30 minutes off her time!

“For my next one, I am training for the 2007 Chicago Marathon and my goal is to complete it in five hours 30 minutes,” said Alison.

Oh yeah, and “Scooter the Cow,” well, you could say Scooter helps Alison with her training too. In her spare time, Alison trains by running from her home to the New York Yankees’ minor league ballpark where she dresses up as “Scooter the Cow” for the fans.

“I like being Scooter. It’s hot in the costume. I’d say it reaches 120 degrees sometimes, but I enjoy it,” happily said Alison.
Diets do not work. Now, there is a statement that got your attention. The diet industry is a multibillion dollar industry. How much money have you contributed to it? Are you ready to STOP?

When people talk about lifestyles, what do you think of? Most people will think of the car they drive, the house in which they live, the restaurants they go to and the friends they have. But, we are here to talk about the lifestyle that affects your health.

We are talking about choices; starting with nutrition, movement, behavior modification and yes, even attitude. Obese people have choices; we do not have to suffer in silence any more. It is a lifestyle that saves us, not a diet. We all can benefit with wellness, no matter what our weight.

This is a journey, not a destination. Remember, we are told to be lifelong learners. Well, that pertains to your health and wellness too!

Educate and Encourage Yourself

First and foremost, you must surround yourself with a strong support system. This starts with your family and community. Support groups are critical for long-term success. If you have groups available, attend them regularly for the latest weight-loss news and personal support and encouragement. If that is not available to you, go to the Web. There are telephone support groups available also – you just have to commit. There are many great sites with free e-mail newsletters and message boards where you can have questions answered by experts and fellow patients alike. You need to make the first move.

Empower and Engage Yourself

Attend weight-loss and wellness conferences whenever possible. These serve to reacquaint you with the tools you have at your disposal and the many people out there just like you. And if you think you need a little help over those bumps in the road, take advantage of professional resources to get the help you need. Read everything you can. Share information with your friends.

Every morning is a new beginning, and you have a choice every morning of the mood you will be in for the day. Your attitude will thank you for it. Remember that smile you saw or small kindness that made your day. Be the one to make someone else’s day. Surround yourself with people who make you happy and think positively.

Exercise and Energize Yourself

Think of movement, and not that nasty four letter word “exercise.” Movement energizes you, whether in the classic gym or more importantly in all that you do each day. Take the stairs, park further out, do housekeeping tasks during TV commercials, change your movement routine frequently, walk when stressed and get a buddy to make you accountable for doing things. Turn on the music and get up and dance.

People ask, “What is the best form of exercise?” The answer: the one you will do! Keep your protein intake up and remember to drink, drink and drink (water that is). You need...
one ounce of clear, non-caloric, non-caffeine liquid every day for every two pounds of body weight. Eat vegetables and occasional fruits in their raw form to get the fiber your body needs. Make movement fun and you will be more likely to do it. Your newfound energy will surprise you.

**Enable and Embrace Your Lifestyle**

Be accountable to yourself. After all, you count the most on yourself. Make a log of all of your food in your “planned eating events.” Log your movement and even those behaviors and feelings that thwart you and those that make good things happen.

Record your monthly weight and measurements. Take frequent pictures, either with people you consider “normal” in appearance or in a physical setting with eye-catchers like door frames to help gauge your relative size. Celebrate the changes you see, but NOT with food.

**Enjoy Yourself**

Eat your food with baby utensils and on eye-catching small plates. If need be, time your bites and put that fork down to enjoy the ambiance and people around you. Make every planned eating event a special occasion. You are important! Remember, your lifestyle must make you happy and healthy.

**Healthy continued from page 5**

One of the biggest reasons people snack on unhealthy convenience foods is because healthy options are not on hand, and you get foods you like! If you hate carrots, do not get yourself baby carrots to snack on. This is especially true when planning snacks for kids – if you want to get your kids to eat a new unfamiliar food, it is best to do this at a supervised meal like dinner or breakfast. If your kids like the snacks they have available to them, they are more likely to eat them and not beg for junk foods.

Just as important when you are planning is that “what not to buy” list. If you fill your cupboards with chips, cookies, soda and other high-calorie, low-nutrient foods, they will often get eaten instead of the healthy snacks. By not having those tempting foods available, you and your family are more likely to eat the foods that are better for you.

**Snacks for Everyone**

Good general ideas for healthy snacks include small servings of protein foods such as:

- Cheese slices
- Nuts and seeds
- Lean sliced meats
- Whole pieces of fruit
- Whole grain crackers

If you like the idea of convenient things that are “grab and go,” look at individual servings of applesauce, low-fat granola bars and small packets of nuts or dried fruits.

**Snacking Resources**

This article provides just a few suggestions for easy, healthy snacks. If you want more ideas, the Internet provides some great resources. Some of my favorites are:

- [www.mealsmatter.org](http://www.mealsmatter.org) - the “Cooking for Your Family” sections has all sorts of great ideas.
- [www.whfoods.com](http://www.whfoods.com) - this is the site for The World’s Healthiest Foods. This is a great place to get ideas for new healthy snack foods.
- [www.familyeducation.com](http://www.familyeducation.com) - this site has a wonderful section on family nutrition with snack and meal ideas.

**About the Author:**

Jacqueline Jacques, ND, is a Naturopathic Doctor with more than a decade of expertise in medical nutrition. She is the Chief Science Officer for Catalina Lifesciences LLC. Her greatest love is empowering patients to better their own health. Dr. Jacques is a member of the OAC National Board of Directors.
Surgical Review Corporation (SRC) gets bombarded daily with questions about bariatric surgery, our Centers of Excellence programs and our recently released outcomes database. We get so many telephone calls and emails each day that we established a Support Center to handle them all in a timely manner.

The number one question we get is WHY? Why should a center apply to the Bariatric Surgery Centers of Excellence (BSCOE) program? Why do surgeons and hospitals need to enter their data into BOLD? Why does BOLD ask so many questions? Why won’t my health insurance pay for my surgery? Why did my surgeon recommend the adjustable gastric band instead of a gastric bypass? Why does diabetes go away after bariatric surgery?

The daily barrage of calls and emails come from patients, their families, the media, health plans, surgeons and program coordinators alike. The subject matter varies but the theme is the same – why?

Everyone wants answers. No one wants to wait. SRC is expected to deliver the answers. Until recently, there wasn’t a single source for answers. Health plans offered few. Think back to the early part of this decade when payors refused to cover bariatric surgery altogether.
Or remember when several health plans began their own Center of Excellence program with conflicting requirements that created confusion throughout the industry about what excellence actually meant.

There were no answers for patients who wanted to know which centers and surgeons could truly provide optimal care. Few answers existed regarding which bariatric surgery was appropriate based upon the patient’s needs and which pre and post-operative care paths were optimal. Questions continued to mount because no one knew where to go for the answers.

Meanwhile, morbid obesity continued to spiral out of control and without a source for answers, consumer confidence in bariatric surgery waned. Media accounts led the public to believe that bariatric surgery was unsafe and the surgeons were crooks. Were these the answers to be used to characterize the entire industry?

In 2003, the membership of the American Society for Metabolic and Bariatric Surgery (ASMBS) responded flatly with, “NO! Our patients deserve better.” As a result, the SRC, a completely independent organization governed by industry stakeholders and the Bariatric Surgery Centers of Excellence program were founded by bariatric surgeons to provide answers. Answers to questions like:

- **What factors distinguish an “excellent” bariatric surgery center?**
  SRC’s Web site lists 10 requirements that must be met. After completing two levels of application, centers and surgeons must pass a site inspection that is considered the most rigorous in the industry.

- **Where can patients go for optimal care?**
  SRC’s Web site lists 276 hospitals and 501 surgeons that meet the BSCOE program requirements. The number grows weekly.

- **How safe is the surgery?**
  Our centers tout an impressive 0.35 percent 90-day mortality rate (verified by site inspections) – a rate lower than most surgeries and comparable to gallbladder surgery. Hard to believe when you consider just how sick most bariatric surgery patients usually are.

- **Has the BSCOE program improved coverage?**
  Some. Last year, Medicare announced that they would provide coverage for bariatric surgery but only if it is performed at an ASMBS BSCOE center or an American College of Surgeons Level 1 center. Other health insurers are starting to come around. Some are now requiring that centers must first be an ASMBS BSCOE before they can become a member of their network. The process has been slow, but SRC is encouraged by recent developments as we continue to work closely with the payors. The excellent work by the surgeons coupled with the ASMBS BSCOE program have been key factors in this progress.

Much progress has been made since this highly successful program began less than three years ago. But many don’t realize that this is only the first step. If SRC’s focus was limited to awarding Centers of Excellence designations, it would fall short of its mission and questions would begin to mount. The BSCOE program answers some of the questions, but the next questions will become more and more complex. Questions such as:

- How do we stratify patient risk factors?
- Which clinical pathways are the most effective?
- How effectively are co-morbidities resolved and durable weight-loss achieved by surgery type?
- What are acceptable outcomes levels, such as mortality and complication rates, to maintain a level of “Excellence?”
- Can payors be convinced that they receive a return on investment if they cover bariatric surgery?
- Are the current BSCOE program requirements suitable for centers to stay excellent in the future?

SRC expects the answers to these and other important questions to come from our recently released Bariatric Outcomes Longitudinal Database (BOLD™). This innovative database will be used to capture detailed information on each patient such as co-morbidities, the type of surgical procedure, adverse events, weight-loss progress and outcomes. All BSCOE program participants are required to report their data and as a result, we expect more than 100,000 patients each year will be entered. BOLD™ is a tool that will be used for improving:

- **Patient care:** Data from BOLD™ will be provided back to surgeons and their staff so they can learn from the results.
- **Coverage:** Finally, surgeons will have better data than most payors. Data that will be verified by site inspection.
- **Patient Safety:** Adverse events will be closely scrutinized.
- **Quality:** BOLD™ will be used to guide future BSCOE program requirements.

Without a central source for answers, bariatric surgeons were headed into perilous territory. But instead of idly sitting by and becoming a victim, they chose to take charge of the situation and establish a program to provide answers. Those in the industry are starting to notice.

Armed with a superior quality program and better data than anyone else in the industry, bariatric surgeons take a giant step closer to being able to answer, “Why?” SRC is simply following doctors’ orders.

**About the Author:**

Gary Pratt is the Chief Executive Officer of the Surgical Review Corporation. Gary graduated from the University of Tennessee with degrees in marketing and accounting. Mr. Pratt has started seven successful businesses and was a partner in a national accounting firm. He is a proud member of the Obesity Action Coalition.
it can be bought without a doctor’s note, it still packs a prescription price. For about $49.99, the Alli Starter Pack™ contains a 20-day supply of Alli™, a carrying case, a meal journal and instructions on the Alli™ plan which emphasizes portion control, counting calories and fat grams and physical activity.

Online resources are also available for the computer-savvy user. After these first 60 pills are consumed, the patient can subsequently buy a 40-day supply “refill pack” – listed for $63.99 on www.drugstore.com – about $1.60 per day of pills. Orlistat users should check with their individual insurance companies to see if these costs are eligible for reimbursement.

How does Alli™ work?

Patients who plan to take Orlistat must be aware of how it works in order to understand its effects on weight-loss and the body. The active ingredient in Orlistat binds to enzymes called lipases, which are responsible for breaking down fats in ingested food so the fat can be absorbed and used by the body.

What are the side effects of Alli™?

Once Orlistat attaches to the lipases, the enzymes no longer work effectively and about 20 percent of the fat you eat does not break down, and thus is not absorbed or used by the body. Instead, the unabsorbed fat travels down the intestines undigested and is excreted in the feces.

As a result, Orlistat users can expect to experience episodes of sudden oily discharge in the stool and increased frequency of defecation after ingestion of fats. These effects are reported by about 25 percent of users, and thus patients are advised to try the medication on a day when he/she can stay close to restroom facilities, wear dark pants and carry a change of clothing to avoid embarrassment should this occur when outside the home.

Though the side effect of sudden fatty discharge and possible abdominal discomfort seems untoward, many users have success in avoiding high fat foods even after discontinuing the drug because they create an association between eating fat and having an awkward accident. In clinical trials, only about 3 percent of patients stopped taking Orlistat because of this side effect.

Pros and Cons of Alli™

Pros
• FDA approved and regulated
• Available over-the-counter
• 50 percent more weight-loss vs. dieting alone*

Cons
• Not recommended for long-term use
• Explosive oily diarrhea
• Vitamin malabsorption

*Per www.myalli.com™

Considering starting Orlistat before beginning the tablets so that appropriate dosage adjustments and monitoring can be arranged.

Finally, patients expecting Orlistat to be “the miracle pill” will likely be disappointed. This medication is best used in a patient highly motivated to lose weight and who is presently on a balanced, low-fat diet and who is regularly exercising. Maximum benefits are usually seen within the first six months, and its usefulness beyond four years has not yet been well studied. Patients are advised to adopt a healthy lifestyle while taking Orlistat and beyond to prevent weight regain. Furthermore, be sure to inform your healthcare professional if you are planning to take Orlistat so he/she can be of assistance in helping you achieve your goals while optimizing your overall health.

Resources:
1. www.myalli.com™
2. www.utdol.com/utd/content/topic.do?topicKey=drug_1_z/58480&selectedTitle=1-12&source=search_result

About the Author:
Holly Lofton, MD, is currently a fellow in the Bariatric Medicine/Nutrition program at Geisinger Medical Center under the direction of OAC Board of Director member Christopher Still, DO. Her primary interests are improving nutrition and activity profiles for overweight and obese patients.

Alli™ logo provided by GlaxoSmithKline Consumer Healthcare.
The weight-loss surgery field experienced exponential growth throughout the past four years. As a result, I find myself being asked more and more questions regarding post-operative surgery. Be it plastic surgery, or a revision, the sheer numbers of post-op patients is increasing the demand for these two types of post-op procedures.

In this article, we’ll talk solely about revisions. And that word, revision, gives rise to a number of included terms such as failed surgery, non compliance and revision to a new procedure.

Revision, defined, is to change or modify (for our purposes, it is to change or modify a prior bariatric surgery). There are several areas where revisions can arise. A patient will be dealing with either a revision of a failed bariatric procedure or a revision to a new type of procedure not approved or even in existence at the time of the original surgery.

Will My Insurance Provider Cover a Revision?

This is a simple question, but a not so simple response. As we all know, insurance companies seem to make decisions by throwing darts at a dartboard. So it’s only natural to assume that a provider will have different responses for different individuals from different states.

To begin, a request for a revision based upon a failed prior bariatric surgery is going to immediately invoke a response from most insurance providers questioning whether the prior surgery actually failed, or the patient was simply not compliant with the requirements of the first surgery. In other words, eating past the pouch or band.

A revision from a prior procedure to a new type of procedure is going to receive similar questions along with the additional question of why the patient is seeking to change from a Roux-en-Y to gastric banding or duodenal switch.

Before you make this type of request, it is imperative that you and your surgeon are on the same page. He or she should be aware of the exact need for the surgery, as well as your compliance issues during the original procedure. Never wait for the insurance company to ask the question. Answer it when your surgeon submits the request for authorization.

If the pouch stretched, staple line failed, band slipped or bypass simply hasn’t worked, you must have the pre-op testing to prove these allegations. Whether an MRI, CT scan or endoscopy, you should have the results before you apply for certification. Likewise, you should provide your surgeon with a general description of your compliance throughout the years, consisting of a diet and exercise history.

Chances are your body mass index (BMI) has been low at times and you no longer have any significant co-morbidities. In this case, you are going to make sure that the carrier knows that if the revision is not granted, it will only be a short matter of time before your BMI climbs even higher and your co-morbidities return. If your request involves a new type of surgery, perhaps one that didn’t exist when you had your original surgery, make sure the reasons why this surgery is right for you are included in the request for surgery. These pre-emptive strikes just may get you the approval you seek by answering the insurance company’s questions before they’re asked.

I know what you’re thinking. Suppose my insurance company does not or no longer covers bariatric or weight-loss surgery. Well, in that situation you’re going to argue two things. First, that weight-loss surgery should be a covered expense because it is used to treat co-morbidities in addition to obesity, such as diabetes or hypertension. And second, that this is a request to correct a failed procedure that may cause significant problems in the near future and as such it is not for obesity or weight-loss. The latter is a tougher argument, but one that has been made successfully.

So remember, like your request for your original surgery, you must document your claims. And, of course, never quit.

About the Author:

Gary Viscio, Esq., is an attorney who specializes in appeals for denials of obesity surgery, reimbursement and coverage, as well as obesity discrimination. In July 2003, he underwent weight-loss surgery and to date has lost more than 160 pounds. He is a member of the Obesity Action Coalition, ObesityHelp Advisory Panel and the Board of Directors of the National Spinal Cord Injury Association. He has handled insurance litigation matters for nearly 15 years.
In February 2006, to much public acclaim, Medicare announced an expansion of its coverage of bariatric surgery. As we look at this ruling nearly more than a year and a half later, a harsh reality becomes evident. Bariatric surgery, in many parts of the country, is no more available today to Medicare beneficiaries than it was prior to the ruling.

Understanding Medicare Coverage
Under Medicare, the Centers for Medicare and Medicaid Services (CMS), the agency that oversees Medicare, hires regional contractors (usually insurance companies) to determine benefit coverage and pay claims for Medicare beneficiaries. The vast majority of decisions on coverage are made at the local level by the regional contractors and not by Medicare itself.

Under this system, prior to February 2006, Medicare coverage for bariatric surgery varied widely. In some parts of the country, coverage was widely available, while in others it was non-existent.

The National Coverage Decision
With this disparity in mind, leaders of the American Society for Metabolic and Bariatric Surgery (ASMBS) along with many others, asked CMS to make a National Coverage Determination (NCD) regarding the surgical treatment of morbid obesity. An NCD requires that all Medicare contractors follow the same ruling. The intent of the NCD was to level the field by applying the same guidelines regarding the availability to and requirements for bariatric surgery.

After a very lengthy and intensive process, a positive NCD was released by Medicare validating bariatric surgery as a safe and effective treatment for morbid obesity and including a number of guidelines, some specific and some vague, regarding both the availability and requirements for bariatric surgery.

The Problem: Regional Contractors Continue to Limit Access
The NCD should have been the solution and granted widespread access to bariatric surgery to appropriately selected candidates, but it hasn’t.

The problem is that the vague guidelines have allowed the regional contractors to interpret and administer the guidelines. As a result, some regional contractors are now developing their own criteria for certain requirements to access bariatric surgery (also called local coverage determination, or LCD). And these requirements, in the opinion of the OAC, are vastly limiting access to care. *(Please see the chart below for examples of how some regional contractors interpret the NCD.)*

Adding to the challenge is also what seems to be a lack of agreement between CMS and the Medicare contractors on who determines and interprets coverage policies. Examples of such vagueness and how Medicare contractors are interpreting the NCD:

<table>
<thead>
<tr>
<th>Medicare NCD States</th>
<th>Medicare Contractor Interpretation through LCD Coverage Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previously unsuccessful with medical treatment for obesity</td>
<td>Documented evidence of repeated failure of multiple attempts (usually 3) of at least 6 months each to lose weight on a supervised non-surgical management weight-loss program. <em>(Contractor with this requirement: Cigna Government Services)</em></td>
</tr>
<tr>
<td>Have at least one co-morbidity related to obesity</td>
<td>Specifically defining co-morbidities. For example, hypertension (defined as blood pressure of 140 mmHg systolic and/or 90 mmHg diastolic) despite medical treatment with maximal doses of three antihypertensive medications. <em>(Contractor with this requirement: Trailblazer Health)</em></td>
</tr>
</tbody>
</table>

*Medicare continued on page 18*
October Issue of “OAC News” Celebrates its 3rd Volume of the Publication

The October 2007 issue of “OAC News” marks the 3rd volume of the patient-focused publication. Since 2005, the Obesity Action Coalition (OAC), has provided readers with the most up to date information in the obesity community and the latest news from the OAC.

Each issue features articles on weight-loss treatments, prevention, obesity-related diseases, nutrition, childhood obesity, advocacy and much more. In addition, each issue features a patient profile which details a patient’s journey and struggles with the disease of obesity. All past articles may be found on the OAC Web site by clicking the “Resources” tab and visiting the “OAC News” section. Past articles may be downloaded and printed for distribution.

More than 15,000 copies of each issue of “OAC News” are distributed nationwide to members of the OAC, patients, surgeons, physicians, dietitians, nurses and a variety of other healthcare professionals.

“OAC News” is available in print and online at www.obesityaction.org. For more information on “OAC News” or to view past issues online, please visit the “OAC News” section on the OAC Web site.

OAC Calls on Insurers and Employers to Increase Access to Obesity Management Services

In light of recent studies in the New England Journal of Medicine (NEJM) demonstrating a powerful connection between obesity interventions and reduced deaths, the Obesity Action Coalition (OAC) calls on insurers and employers to increase access to the treatments of obesity and morbid obesity.

In one study, led by Ted D. Adams, PhD, MPH, staggering results were reported in regards to the occurrence of death due to cancer, cardiovascular events and diabetes. The study concluded that long term total mortality after gastric bypass was significantly reduced. This is one of the first major studies demonstrating that intentional weight-loss leads to improved life expectancy.

“Obesity is not a cosmetic problem. As demonstrated in the NEJM studies, obesity interventions such as bariatric surgery save lives. It is now time for all insurers and employers to make obesity management services a priority and widely available to those affected by the diseases of obesity and morbid obesity. By doing so, those affected by obesity and their healthcare providers will have the necessary tools to combat this lifelong disease and improve the longevity and quality of health and life for all those affected by obesity,” said Joseph Nadglowski, Jr., OAC President and CEO.

Obesity is a serious health epidemic that targets one in four Americans. It is estimated that more than 93 million Americans are obese, with that number predicted to climb to 120 million in the next five years. In order to address this epidemic, the OAC recognizes and promotes increasing prevention efforts and improving access to safe and effective treatment options, such as nutrition counseling, physician supervised weight-loss (with or without pharmaceuticals) and for appropriately selected candidates, bariatric surgery.
Medicare: continued from page 16

Working to Improve Access
So how do we improve coverage? The OAC, in partnership with the ASMBS and others, is actively fighting this battle on many fronts. First, we continue to work with Medicare and CMS and advise them of major challenges patients experience accessing care.

We have begun working with the Medicare contractors advising them if we believe their policies are unfair or lack scientific basis. To date, we have had some limited success with the Medicare contractors but also have been told by some that they are not interested in revising their policies. As a result, we are now also considering further action on both the legal and legislative front to force local intermediaries to follow the spirit of the NCD.

Improving Medicare Access is Important
Medicare issuing an NCD was just the first step. We must actively continue to ensure that Medicare beneficiaries have access to bariatric surgery. Why is it so important? Remember that most commercial insurers follow Medicare’s lead when it comes to coverage and policies. As such, fixing Medicare’s coverage not only helps Medicare beneficiaries but also all of those seeking to access treatment for their morbid obesity.

If you have been personally affected by a Medicare contractor’s LCD or have been unable to access bariatric surgery under Medicare, please share your story with us by calling (800) 717-3117 or e-mailing us at info@obesityaction.org.

We need to hear from you so we can share your story with Medicare as well as others supporting our efforts to improve care.

Call to Action

Chairman’s Council
The OAC is grateful for the generous support of its Chairman’s Council Members:

Platinum
($100,000 and up)
Allergan, Inc.
ASMBS Foundation
Covidien
Ethicon Endo-Surgery

Gold
($50,000)
American Society for Metabolic & Bariatric Surgery

Silver
($10,000)
Bronze
($5,000)
Patron
($1,000)

Bariatric Support Centers International
John W. Baker, MD
Dakota Clinic - Park Rapids
Jim Fivecoat
Geisinger Health Care System
Lee Grossbard, MD
Medifast, Inc.
Medi-Weightloss Clinics
National Association of Bariatric Nurses (NABN)
New Dimensions Weight Loss Surgery
Gregory L. Schroder, MD
Scottsdale Bariatric/Scottsdale Healthcare
SmartForme

The Chairman’s Council is the OAC’s most prestigious membership level. Membership in the Council is accompanied with several exclusive benefits. By joining as a Chairman’s Council member, you are making a commitment to improving education and advocacy efforts for the obese and morbidly obese. Most importantly, your membership strengthens the voice of patients in the obesity community.

To add your name to this list, please visit www.obesityaction.org or contact us at (800) 717-3117.
OAC Membership

The OAC was founded as the “patient voice” in obesity. As a membership organization, the OAC exists to represent the needs and interests of those affected by obesity and provide balanced and comprehensive education and advocacy resources. Membership in the OAC is integral in strengthening the voice of the millions affected by obesity. Various membership levels are available and each is accompanied with several valuable benefits such as:

- Official membership card/certificate
- Annual subscription to OAC News – OAC’s quarterly educational and advocacy newsletter
- Subscription to Obesity Action Alert – monthly e-newsletter distributed on the 1st of each month

Yes! I would like to join the OAC’s efforts. I would like to join as a/an:

- [ ] Patient/Family Member: $20
- [ ] Professional Member: $50
- [ ] Physician Member: $100
- [ ] Surgeon Member: $150
- [ ] Institutional Member*: $500 (Surgery centers, doctors’ offices, weight-loss centers, etc.)
- [ ] OAC Chairman’s Council*: $1,000 and up * These membership levels have exclusive benefits.

Name: __________________________
Company: _______________________
Address: _________________________
City: ___________ State: _______ Zip: ___________
Phone: ___________ Email: ___________

Payment Information
Enclosed is my check (payable to the OAC) for $ _________.
Please charge my credit card for my membership fee:

- [ ] Discover®
- [ ] MasterCard®
- [ ] Visa®
- [ ] Amex®

Credit Card Number: ___________
Expiration Date: ___________
Billing Zip Code: ___________

Mail to: OAC
4511 North Himes Ave., Ste. 250
Tampa, FL 33614
(813) 873-7838

Or Fax to: ________________________

Gallbladder continued from page 3

intestine at the bottom of the stomach. This complication is reported to occur in 0.5-2 percent of patients undergoing a cholecystectomy and can be a life threatening complication. Some studies suggest that this complication is more likely to occur in difficult cases; difficulty often caused by excessive obesity in a patient.

In addition, for laparoscopic bariatric operations, the placement of the operating trocars (the little tubes that the instruments are passed through during the operation) do not exactly coincide for both a cholecystectomy and a bariatric operation; therefore, the cholecystectomy is more difficult than normal due to reduced visibility and accessibility to the gallbladder from the mal-positioned trocars.

There is also an inherent increased risk when combining two major surgeries, especially given the complexity and length of a bariatric procedure. With the postoperative difficulty associated with an open cholecystectomy, the measure of risk versus benefit does lean toward removing the gallbladder at the time of the bariatric operation. But since today most cholecystectomies are done laparoscopically, the risk of the combined procedures outweighs the benefit of avoiding a possible future operation in a minority of patients.

What is the Consensus?

Looking at all of the information provided in this article, there should be no routine decision made as to whether an obese patient’s gallbladder should be removed. If a patient has experienced symptomatic gallstones prior to choosing their treatment therapy, then it is logical and appropriate to perform a cholecystectomy either before or concurrently with the treatment option.

However, the main debate concerns patients with either no stones or asymptomatic gallstones. If the patient is undergoing a laparoscopic bariatric procedure, then the gallbladder should be left intact. The gallbladder can be easily removed if it becomes symptomatic, most likely when the patient has lost weight from a bariatric operation and is using an operative approach designed specifically to remove the gallbladder. This will expose the smallest group of patients to the least amount of risk for the given procedure.

If the patient has documented asymptomatic gallstones and is not a candidate for laparoscopic surgery, then the decision of whether to remove the gallbladder at the time of the bariatric procedure is ultimately a choice for the patient to make after being properly informed of the risks associated with the surgeries.

An additional option available is to use a medication designed to dissolve gallstones during the rapid weight-loss phase and thus treat the problem before it exists. In theory this makes sense, but in practice many patients forget to take the medication and still develop the gallstones.

About the Author:
Douglas O. Olsen, MD, FACS, is a private practice bariatric surgeon who is the Medical Director for the Centennial Center for the Treatment of Obesity in Nashville, TN. He is a member of the American Society for Metabolic and Bariatric Surgery and is recognized along with the Centennial Center for the Treatment of Obesity as an ASMBS Center of Excellence.
**About the OAC**

The Obesity Action Coalition (OAC) is a non profit patient organization dedicated to educating and advocating on behalf of those affected by obesity, morbid obesity and childhood obesity. The OAC distributes balanced and comprehensive patient educational materials and advocacy tools.

The OAC believes that patients should first be educated about obesity and its treatments and also encourages proactive patient advocacy. The OAC focuses its advocacy efforts on helping patients gain access to the treatments for obesity. As a membership organization, the OAC was formed to bring patients together to have a voice with issues affecting their lives and health. To learn more about the OAC, visit [www.obesityaction.org](http://www.obesityaction.org) or contact us at (800) 717-3117.

**OAC Resources**

The OAC provides numerous beneficial resources for patients, as well as professionals. All OAC resources are complimentary and may be ordered in bulk. To request materials, please contact the OAC National Office at (800) 717-3117 or send an email to info@obesityaction.org.

**Newsletters**

- Obesity Action Alert - the OAC’s free monthly electronic newsletter
- OAC News - OAC’s quarterly education and advocacy newsletter

**Brochures/Guides**

- Are you living with Obesity? Brochure
- Advocacy Primer: Your Voice Makes a Difference
- BMI Chart
- OAC Insurance Guide
- State-specific Advocacy Guides
- Understanding Obesity Series
  - Understanding Obesity Brochure
  - Understanding Obesity Poster
  - Understanding Morbid Obesity Brochure
  - Understanding Childhood Obesity Brochure
  - Understanding Childhood Obesity Poster
  - Understanding Obesity Stigma Brochure

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**OAC News**

The Obesity Action Coalition’s Quarterly Newsletter

Obesity Action Coalition
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Tampa, FL 33614