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This issue of the Rhode Island Medical Journal deals with obesity and is meant for the practicing physician to get an up-to-date overview of available preventative community services from the State of Rhode Island and evidenced-based treatment modalities.

Obesity is a major personal health, society and economic problem in the United States, where, according to the Centers for Disease Control, more than one third (36.5%) of adults have obesity. In Rhode Island, about 25%, or about 200,000 persons, have obesity. Every practicing physician sees several obese patients per day. The most recent estimated annual medical cost of obesity in the U.S. was $147 billion in 2008 – $1,429 per obese person per year higher than for those of normal weight.1

Obesity has been considered a disease by the American Medical Association since 2013. A person’s weight status is categorized by the Body Mass Index, BMI, which is an imperfect measure, but the one that is easiest and most widely accepted. A person with a BMI of 25–30 is considered overweight and a BMI above 30 is considered obese. Obesity itself is classified into Class 1 (BMI 30–35), Class 2 (BMI 35–40) and Class 3 (BMI above 40).

The importance of obesity lies in the systemic effects it has on almost all body systems. It creates an inflammatory state, increases insulin resistance, causes fat accumulation in organ systems such as heart and liver and causes mechanical problems such as back and lower extremity degenerative disease and obstructive sleep apnea. It affects the body from head (increased migraine) to toe (gout and diabetic foot).

The causes of obesity are multifactorial: genetic, societal, cultural, behavioral, and medical. In general, there is an oversupply of calories in proportion to energy expenditure. Over the years, the pendulum of opinion has swung from blaming too much fat intake to too much sugar intake. Although there certainly is a difference in the metabolic effects of various nutrients, there is not one single food group to blame.

The approach to overweight and obesity is also multifaceted because there is no single cause, there is no single symptom constellation and the overweight can range from a few to several hundred pounds. There is also no agreement among researchers about cause, effect and best treatment. In the primary care office the discussion about a person’s weight is a sensitive issue and therefore not an easy one and requires more time than most physicians can afford. For that reason, it is a huge market for non-scientific approaches.

There are a number of scientifically well-researched and successful treatment options available. The choice of treatment option should be individualized to each patient.

In this issue, Dieter Pohl, MD, and Aaron Bloomenthal, MD, from the Metabolic and Bariatric Surgery Center at Roger Williams Medical Center, outline the surgical options for the treatment of obesity and the results on comorbidities. Stephanie Curry, MD, endocrinologist and obesity medicine specialist at CharterCARE Medical Associates and Roger Williams Medical Center, presents additional treatment options with a rapidly expanding field of weight-loss medications. The FDA has approved more than six medications over the past few years after a dormant period of more than a decade.

Kayloni Olson, MA, Dale Bond, PhD and Rena Wing, PhD, from the Weight Control and Diabetes Research Center at The Miriam Hospital, describe the behavioral approaches to the treatment of obesity, including lifestyle, nutrition and activity modifications.

Dora M. Dumont, PhD, MPH; Kristi A. Paiva, MPH and Eliza Lawson, MPH, from the Rhode Island Department of Health, explain the relevance of obesity, specifically for Rhode Island and the importance of prevention. In this article they provide information on how physicians can address the obesity epidemic with the help of the Community Health Workers program.

Hollie Rousseau, AGACNP, and Dieter Pohl, MD, demonstrate the importance of quality-improvement programs for this high-risk population.

References


Guest Editor

Dieter Pohl, MD, FACS, FASMB, Director, Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) Accredited-Comprehensive Center; Division Director, General Surgery, CharterCARE Medical Associates, Roger Williams Medical Center, Department of Surgery, Providence, RI.
Diabetes, Obesity, and Other Medical Diseases – Is Surgery the Answer?

DIETER POHL, MD, FACS, FASMBS; AARON BLOOMENTHAL, MD, FACS

ABSTRACT

For many physicians, the concept of surgery as the best treatment for a medical disease such as diabetes, cardiovascular problems, hyperlipidemia, sleep apnea, hepatosteatosis, GERD, osteoarthritis, psoriasis, rheumatoid arthritis, or infertility, still sounds wrong and just a ploy by surgeons to increase their business. Since 2011, however, several non-surgical societies have recommended Weight Loss Surgery – The International Diabetes Federation, The American Diabetes Association, American Heart Association, and Obesity Society in 2015 for patients with body mass index (BMI) greater than 35 and diabetes, and to decrease cardiovascular risk factors. The concept is to treat the common underlying problem, which is obesity, with the most effective method for immediate and long-term weight loss, which is surgery. The term “metabolic” surgery was therefore coined to accurately describe the effects of weight loss (bariatric) surgery. Our specialty society named itself the American Society for Metabolic and Bariatric Surgery (ASMBS).

KEYWORDS: bariatric surgery, diabetes, hypertension, mortality, disease

INDICATION AND RISK

Surgery is indicated for patients with a Body Mass Index (BMI) of 35 or higher and obesity-related comorbidities or for patients with a BMI of 40 or higher without comorbidities. Currently, the surgeries are done almost exclusively laparoscopically, by experienced surgeons at American College of Surgeons (ACS) designated Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) Accredited-Comprehensive Center. With these standards, the complication rate has decreased to 3% for diabetes, which is the same as gallbladder surgery and much lower than for total knee replacement (16%), leg bypass (24%) or heart bypass (47%) in otherwise similar populations.

In our MBSAQIP Accredited-Comprehensive Center, the morbidity rate in the last 12 months was 2.7% with half of these due to nausea only. Readmission rate was 3%, reoperation rate 0.3% and mortality has been 0% since 2003 for primary bariatric procedures and no previous surgery in the abdomen.

TYPES OF SURGERY

The ASMSB estimates that in the US in 2015 bariatric surgery was performed on 196,000 patients. This represents only 1.25% of all estimated 16Mill patients with BMI greater than 40. The types of bariatric surgery have changed over the years. In 2015 the majority of surgeries involved the sleeve gastrectomy with 54%, then the Roux-en-Y gastric bypass with 23%. The rest were revisions, gastric band, biliopancreatic diversion, balloons etc.

Laparoscopic Sleeve Gastrectomy (SG)

The sleeve gastrectomy has been used since early 2000. It consists of a resection of about 75% of the stomach, leaving behind a thin stomach from the esophagus to the pylorus. The resulting stomach resembles a banana and holds about 2-3 oz. The effect is a marked decrease in portion size and the loss of hunger during the first year. Some patients will not feel hungry for years due to a lack of Ghrelin, the hunger hormone, which was produced in the removed part of the stomach. There is also a metabolic effect as a result of faster passage of food through the new, smaller stomach. Food reaches the duodenum, jejunum and ileum faster and in a less digested fashion. This in effect leads to an increased production in glucagon-like peptide 1 (GLP1), gastric inhibitory polypeptide (GIP), peptide YY (PYY), and other digestive enzymes, which help in improved regulation of glucose homeostasis. Long-term side effects are rarely seen and limited to Vitamin B12 and iron deficiency.

Laparoscopic Gastric Bypass

The gastric bypass has been performed since the 1960s in various forms and in the current laparoscopic form since 1993. It consists of the creation of a 15-30cc new stomach – resembling a thumb –, and the stapling, cutting and reorganization of the jejunum. The result is that food passes from the esophagus through the small stomach pouch, through a narrow anastomosis directly into the jejunum. Food bypasses the old stomach remnant, the duodenum, and the proximal jejunum. The result is a marked decrease in portion size, a loss of hunger due to the decreased production of Ghrelin, and an even more beneficial change in the homeostasis of many humoral factors such as GLP1, GIP, PYY than in the sleeve gastrectomy that lead to the positive effect on many medical problems. There are also changes of nerve pathways and the microbiome after the gastric bypass, which lead to metabolic changes and eating behavior modification.
Long-term side effects are infrequent and involve iron deficiency, hypoglycemia, and anastomotic ulcer.

Other Surgeries
The gastric band was used frequently in the past, but has recently been used rarely because it does not provide significant, short or long-lasting effects in many patients but leads to further operations in 50% of the patients to either treat problems or to remove the band completely with or without another weight loss operation. Only a few surgeons in RI still offer the band.

The biliopancreatic diversion, duodenal switch surgery is very effective but leads to more malabsorption and requires intense follow-up. This surgery is not performed anywhere in New England.

The balloons have been approved in the USA for about one year. They are approved by the FDA for persons with BMI 30-40, and lead to weight loss of 10-20%. They need to be removed after 6 months, at which point the patient needs to have changed their lifestyle to maintain weight loss, and are currently not covered by insurance. At this time, Roger Williams Medical Center is the only program that offers the balloon.

WEIGHT LOSS
Sleeve gastrectomy and gastric bypass patients lose weight in a similar fashion. As opposed to every other weight-loss method, 100% of patients lose weight for several years, which initially happens fast and continues for about a year. After the first year, the average weight loss is about 70% of excess weight. More importantly, after 5 years the average weight loss is still about 50-70% of excess weight.

Stated differently, as percentage of total body weight lost, The Swedish Obesity Subjects trial (SOS), which looked at 2010 surgical patients and at 2037 non-surgical patients and has a >90% follow-up rate, shows total weight loss for gastric bypass to be at 32% after 2 years, 25% after 10 years, and 27% after 15 years. Weight loss stayed stable after 8-10 years. The matched control group that did not have surgery had weight loss of 0%, 1%, and -1% at these time intervals.5

METABOLIC MEDICAL DISEASE IMPROVEMENTS AFTER SURGERY

Diabetes Type 2
We frequently see that patients who are on oral diabetes treatment and often even on insulin, are discharged after surgery off all medications.

The SOS has the best long-term data. The remission rate after weight-loss surgery was 72% at 2 years, 36% at 10 years, and 30% at 15 years, compared to 21, 13, and 7% respectively for the control group of patients without surgery.6 Even in poorly controlled diabetics with a HgbA1C of >9%, the complete remission to a HgbA1C <6% was achieved in 42% after gastric bypass and 37% after sleeve gastrectomy compared to only 12% of patients with intense medical therapy.7 Surgery also prevented the occurrence of diabetes overall with a relative risk reduction of 78%. There were also decreased microvascular and macrovascular complications. Although the impact of surgery on diabetes is unfortunately not perfect, surgery is clearly more beneficial in the short and long term.

Mortality
The mortality rate for obesity surgery is very low (0.3%). In our hospital it was 0% since 2003 for primary bariatric procedures and no other surgery in the upper abdomen. In addition, many studies have shown that the survival benefit for patients begins within 2 years of surgery. Several studies have shown a reduction in the 5-year relative risk of death from 50% up to 89%. The relative risk for a surgical patient to die was only 0.11 compared to a non-surgical patient. This means the risk for an obese patient to die without surgery is up to 8 times higher than with surgery.2,5,8

Hypertension
We frequently discontinue or reduce anti-hypertension medication at discharge from the hospital, because patients report dizziness and light-headedness at home due to lower blood pressure. Hypertension is either in complete remission or improved in 60-70% even after 5 years.1

Osteoarthritis
Weight causes a high amount of pressure on joints and lower extremity and back pain is frequently seen in obese patients. Obesity surgery decreases the number of patients who report joint pain by 50%, even years after the surgery. Furthermore, many orthopedic surgeons will not perform arthroplasties or back surgery above a certain BMI. Besides the fact that complication rates for arthroplasty are much higher than for weight-loss surgery, the arthroplasty also does not lead to a comparably good result in a morbidly obese person compared to a non-obese person. A recent study showed that bariatric surgery two years before a knee replacement tends to lead to fewer complications, and improved quality of life after the knee replacement.9

Fatty liver
Almost all male patients and the majority of female morbidly obese patients have at least nonalcoholic fatty liver disease [NAFLD], but in about 30% the fatty liver disease has progressed to nonalcoholic steatohepatitis [NASH], and rarely cirrhosis.10 Depending on the stage of the disease obesity surgery leads to either complete resolution of NAFLD or improvement of fibrosis and inflammation. Liver disease due to obesity is becoming one of the most frequent reasons for liver transplant. Prevention with obesity surgery is extremely beneficial.

Hyperlipidemia
A joint scientific statement by the National Lipid Association, the Obesity Medicine Association and the ASMS published in the January/February 2016 issue of the journal
of Clinical Lipidology states that bariatric surgery is effective in improving cholesterol and lipid levels, which are important risk factors for cardiovascular disease.\textsuperscript{9}

**Sleep apnea (OSA)**

Obesity is the cause of more than 50% of sleep apnea cases. CPAP treats OSA but the patient adherence is not very good and CPAP does not treat the cause. Weight loss is the most successful treatment of OSA. Weight loss surgery results in the highest weight loss and best weight maintenance and consequently in the most successful OSA treatment.

**Cancer**

The SOS and other studies also looked at cancer incidence. Overall the relative risk of cancer after surgery was 0.55%. In other words, patients after obesity surgery get only half as many cancers as patients without surgery. Surprisingly, this benefit was almost exclusively seen in women. Men had hardly any benefit.

**Rheumatoid arthritis**

In a group of patients the remission rate was 26% before surgery and at a mean of 5.8 years after surgery 74%. ESR, CRP and related medicines were lower as well.\textsuperscript{10}

**Other**

We also see many other diseases improve after surgery such as infertility, GERD, asthma, shortness of breath, and pseudotumor cerebri. There are reports of 100% restoration of menstruation in polycystic ovarian syndrome PCOS and 50% reduction of migraine days.

**COST**

The many benefits of weight-loss surgery are also reflected in a decrease in patient care cost. A recent study showed that bariatric surgery decreases cost per patient after surgery. The cost decrease for each of 4 years post-op was 12% for the first year, 28% for the second year, 37% for the third year, and 35% for the fourth year. This amounted to \$7,592 over 4 years. For diabetics the cost decrease was 23%, 49%, 61%, 69%, respectively, and \$22,609 total.\textsuperscript{13}

**SUMMARY**

In summary, bariatric surgery is currently one of the lowest risk surgeries and produces greater long-term benefits than any other intervention for obesity.

**References**


**Authors**

Dieter Pohl, MD, FACS, FASMB, Director, Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) Accredited-Comprehensive Center, Division Director, General Surgery, CharterCare Medical Associates, Roger Williams Medical Center, Department of Surgery, Providence, RI

Aaron Bloomenthal, MD, FACS, Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) Accredited - Comprehensive Center, CharterCare Medical Associates, Roger Williams Medical Center, Department of Surgery, Providence, RI.

**Disclosures**

None

**Correspondence**

Dieter Pohl, MD
1539 Atwood Ave., Johnston, RI 02919
401-521-6310
Obesity Epidemic: Pharmaceutical Weight Loss

STEPHANIE A. CURRY, MD

ABSTRACT
Obesity is a chronic disease universally defined as an excess of adipose tissue resulting in body mass index (BMI) ≥ 30.0 kg/m². Over the past few years, the concept of prevention has gained increased awareness, thus leading to the development of additional pharmaceutical options for the treatment of obesity since 2012. Treating obesity revolves around an individualized, multi-disciplinary approach with additional focus on a healthy and supportive lifestyle to maintain the weight loss.

KEYWORDS: obesity, morbid obesity, overweight, anti-obesity therapies, weight-loss medications

THE IMPORTANCE OF MEDICAL WEIGHT LOSS
In 2008, the World Health Organization reported that more than 1.4 billion adults were overweight, BMI > 25 kg/m², and more than half a billion were obese.¹ This global epidemic has led to growing concerns, for adults, and for the increased rate in childhood obesity that predisposes them to become obese adults.² Prevention is imperative regardless of age.

Initiating lifestyle interventions, including behavioral modifications, diet and exercise are recommended first-line approaches for anyone with a BMI ≥25 kg/m². Anti-obesity medications have been approved for use in conjunction with the above mentioned lifestyle interventions for patients with a BMI ≥ 30 kg/m² with no co-morbidities and those with a BMI ≥ 27 kg/m² with obesity related co-morbidities.²,³ Weight related co-morbidities include metabolic syndrome, pre-diabetes, type 2 diabetes mellitus, dyslipidemia, hypertension, nonalcoholic fatty liver disease, polycystic ovarian syndrome, female infertility, male hypogonadism, obstructive sleep apnea, asthma/reactive airway disease, osteoarthritis, urinary stress incontinence, gastroesophageal reflux disease and depression.²

There have been an increasing number of prominent medical studies displaying the benefits of medical weight loss. The Diabetes Prevention Program Research Group performed a large, randomized clinical trial which displayed a reduction in progression from impaired glucose tolerance to type 2 diabetes mellitus with both metformin and lifestyle changes, focusing on diet and exercise.⁴ This study clearly showed that type 2 diabetes mellitus can be prevented or delayed for high-risk patients, such as those who are obese.⁴

OBESITY THERAPEUTIC INTERVENTIONS
There are now multiple clinical practice guidelines published from various societies endorsing medical weight loss. Recently, the American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) published the clinical practice guidelines for comprehensive medical care of patients with obesity.

Currently, there are a total of 6 FDA-approved anti-obesity medications on the market. This is a very exciting time, because since 2012, there have been 4 new agents approved for use by the FDA.

When treating patients with weight-loss medications, as with all medications, it is important to remember that there may be a wide heterogeneity of responses. The goal of obesity medications is to see a 5-10% decrease in weight within the first 6 months of therapy. If there is < 5% weight loss in 3-6 months, it is recommended to consider a dose adjustment or discontinue the medication.

ORLISTAT
Orlistat, also known as Xenical, is a non-systemic, gastric and pancreatic-lipase inhibitor that was approved in 1999. By inhibiting pancreatic lipase, it blocks the absorption of approximately 30% of dietary fat.⁶ At 1 year, patients treated with orlistat had a 4.0% decrease in body weight compared to placebo.² Several randomized controlled trials, ranging from 2–4 years in duration showed long-term weight reduction, in addition to improvement in blood pressure, insulin resistance and serum cholesterol levels.⁷,⁸ It is dosed three times a day before meals. A co-prescription for fat soluble vitamin supplementation including A, D, E and K is recommended, given the mechanism of inhibiting fat absorption to prevent deficiencies.⁶,⁸

The main disadvantage is the side effect profile with a higher incidence of unpleasant gastrointestinal adverse effects including abdominal pain, bloating, diarrhea, flatulence, steatorrhea, fecal incontinence and dyspepsia.⁷,⁸ Contraindications to use include chronic malabsorption, cholestasis, oxalate nephrolithiasis, pregnancy, and breastfeeding.³

PHENTERMINE
Phentermine, also known as Adipex-P, is a sympathomimetic that was approved for monotherapy in 1959.⁹,¹⁰ This is
Belviq had 3.0-3.6% decrease in total body weight compared to placebo.² Belviq is dosed twice a day and more recently as extended release, once a day formulation has become available called Belviq XR.

It has a fairly favorable side effect profile and is generally well tolerated. Adverse effects include headache, nausea, diarrhea, constipation, dizziness, fatigue, xerostomia, dry eye, hypoglycemia, headache, back pain and cough.⁸,¹⁰ It was also associated with improvements in hyperlipidemia, insulin resistance, levels of inflammatory markers and hypertension.¹⁰ Contraindications include the use of other serotonergic drugs due to concern for serotonin syndrome, pregnancy and breastfeeding.²

**CONTRAVE**

ContraVe, a combination of naltrexone and bupropion extended release, was approved in 2014. Naltrexone is a non-selective opioid receptor antagonist and bupropion is an inhibitor of dopamine and norepinephrine transporters. Together, the two medications in combination revealed a synergistic effect by producing a greater reduction in food intake and appetite regulation, thought to involve the food reward mechanism.⁸ At 1 year, patients treated with ContraVe had a 4.2–5.2% decrease in total body weight compared to placebo.²

Adverse effects are consistent with the known adverse effects of the two medications individually, including nausea, vomiting, constipation, headache, insomnia, diarrhea, dizziness, anxiety and xerostomia.²,¹¹ Contraindications include uncontrolled hypertension, seizure disorder, tachyarrhythmia, severe depression, chronic opioid use, concomitant use of MAO inhibitors, anorexia or bulimia nervosa, drug or alcohol withdrawal, liver failure, narrow angle glaucoma, pregnancy and breastfeeding.²,⁸,¹¹ It is recommended to discontinue this medication gradually and avoid abrupt cessation given the lowered seizure threshold associated with bupropion.

**SAXENDA (LIRAGLUTIDE)**

Saxenda, also known as liraglutide, is the only long-acting, daily, injectable therapy approved for medical weight loss. It is a glucagon-like peptide-1 (GLP-1) receptor agonist that was approved in 2014. It previously was approved at a lower dose by the FDA for treatment of type 2 diabetes mellitus, known as Victoza. The mechanism of delaying gastric emptying and agonist effects on GLP-1 receptors in the brain have been implicated in decreasing appetite thereby decreasing caloric intake.⁸,¹¹ At 1 year, patients treated with saxenda had a 5.6% decrease in total body weight compared to placebo.² It has also been shown to improve fasting and postprandial glycemia, beta-cell function, insulin sensitivity and delayed onset of type 2 diabetes mellitus.¹¹ This is the most expensive medication on the market, costing approximately $1100 monthly if the employer has not opted into coverage which has limited its use.
Adverse effects include nausea, vomiting, diarrhea, constipation, headache, increased heart rate, dyspepsia and hypoglycemia. Contraindications for use include gastroparesis, personal or family history of medullary thyroid cancer, acute gallbladder disease, pregnancy and breastfeeding. The dose of this medication is titrated based on tolerability of adverse effects. Thyroid C-cell tumors have been reported in rodents only; however, the FDA has required a boxed warning of contraindication for patients who have a personal or family history of medullary thyroid cancer or those with multiple endocrine neoplasia syndrome type 2 (MEN 2). The significance in humans is unclear and ongoing post-marketing evaluations are planned to evaluate the incidence of medullary thyroid cancer and the potential risk of breast cancer. 8,12

CONCLUSION

The CDC estimates that each year at least 2.8 million people die secondary to being overweight or obese. Both awareness and prevention is the cornerstone of treatment for this disease. Obesity medications have proven to be a favorable, additional therapeutic intervention to complement diet, behavior modifications, physical activity and bariatric surgery. Hopefully, continued awareness, dedication and research will bring more options for providers and patients to treat obesity.

References

Author
Stephanie A. Curry, MD, Division of Endocrinology, Diabetes and Metabolism, CharterCARE Medical Associates, Providence RI.

Disclosures
None

Correspondence
Stephanie A. Curry, MD
1539 Atwood Ave, Suite 304
Johnston, RI 02919
401-519-3336
stephanie.curry@chartercare.org
INTRODUCTION
Behavioral (or lifestyle) interventions are considered the cornerstone of obesity treatment. These programs are designed to produce long-term weight losses through changes in diet and physical activity. Behavioral approaches form the basis for the prevention and treatment of obesity in both children and adults. In addition, they are critical components of pharmacological and surgical approaches to obesity.

The Weight Control and Diabetes Research Center, which is affiliated with The Miriam Hospital, conducts research to develop and evaluate new behavioral approaches to weight control [http://weightresearch.org]. Participants entering these research studies receive state-of-the-art behavioral programs at no cost.

COMPONENTS OF A BEHAVIORAL WEIGHT LOSS PROGRAM
Lifestyle programs are designed to help patients lose 1–2 pounds per week resulting in a 5–10% weight loss by 6 months. Subsequent efforts are focused on maintaining the weight loss or if desired, losing additional weight. Such weight losses are realistic for patients and as will be discussed below, produce important health benefits. To accomplish these weight changes, behavioral programs include the following components,1 which are summarized in Table 1.

Diet Interventions
Weight loss requires an energy, or calorie, deficit, created primarily through restriction of dietary intake. Patients are given individualized calorie goals to produce a 500 to 1000 kilocalorie (kcal) deficit from their baseline intake and thus produce a 1–2 pound per week weight loss. In most programs, individuals under 200 lbs are prescribed a 1000–1500 kcal/day diet, whereas those over 200 lbs are given a 1500–1800 kcal/day goal. Although there are extensive data that weight loss is primarily related to caloric restriction rather than to the macronutrient composition of the diet, behavioral programs typically encourage participants to reduce fat intake (< 30% of calories from fat) to help achieve the calorie goal. Weight loss can be achieved with a low fat or low carbohydrate diet, as long as the diet produces a decrease in overall calories consumed. Since adherence to diet prescription and reduction in calorie intake is critical, behavioral programs often include use of meal replacement products or structured meal plans to help patients adhere to the calorie goals. Self-monitoring of intake also is a key component (see below).

Physical Activity
Behavioral programs encourage gradual increases in physical activity using moderate intensity activities such as brisk walking. The goals for physical activity typically start at 50 minutes/week, but they are gradually increased to 150 minutes/week, with patients encouraged to achieve this goal over 5 days in the week. Reaching these goals can be done in short bouts of 10 minutes and accumulated over the course of the day. Recent data suggest that even higher levels of physical activity (200–250 minutes per week) are associated with better maintenance of weight loss; thus programs now encourage participants to try to achieve these higher goals. In addition, patients are encouraged to identify and decrease sedentary behaviors, particularly watching television given its association with increased intake of energy dense foods. This is in addition to finding ways to increase lifestyle (or non-structured) physical activity such as using stairs rather than elevators. It remains unclear whether using contemporary fitness tracking devices [such as a FitBit] are helpful in promoting adherence to the physical activity goal and improving weight loss outcomes.2

Table 1. Key components of a Behavioral Weight Loss Program

<table>
<thead>
<tr>
<th>Calorie Restriction</th>
<th>Individualized calorie goals to produce a 500 to 1000 kcal deficit from baseline</th>
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<tr>
<td></td>
<td>• Those &lt; 200 lbs: prescribed a 1000–1500 kcal/day diet,</td>
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<td></td>
<td>• Those &gt; 200 lbs: prescribed a 1500–1800 kcal/day diet</td>
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<td></td>
<td>• Reduce fat intake to help achieve calorie goals</td>
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<tr>
<td>Physical Activity</td>
<td>Increases in moderate intensity activities such as brisk walking</td>
</tr>
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<td></td>
<td>• Begin with 50 minutes/week (10 min on 5 days in the week)</td>
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<td></td>
<td>• Gradually increase to 150 minutes/week (30 minutes on 5 days in the week)</td>
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<td></td>
<td>• For better maintenance of weight loss, increase further to 200 or 250 minutes/week</td>
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<tr>
<td>Behavioral Strategies</td>
<td>Behavioral strategies to increase adherence to the diet and activity goals</td>
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<tr>
<td></td>
<td>• Self-monitoring (recording weight, diet and activity on a daily basis)</td>
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<td></td>
<td>• Stimulus control (removing high calorie foods from the home)</td>
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<td></td>
<td>• Goal setting, preplanning, and problem solving areas</td>
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Behavioral Strategies
To help patients make and sustain the prescribed changes in eating and activity behaviors a variety of behavioral strategies are used, chief of which is self-monitoring. Self-monitoring, or recording of weight, diet and activity on a daily basis has been shown to be the most important component of a behavioral weight loss program. Participants are encouraged to weigh themselves daily so that they can see the relationship between their eating and activity and their body weight. Other behavioral strategies include stimulus control (removing high calorie foods from the home and making certain that low calorie, healthy options are available), goal setting, preplanning, and problem solving. These strategies, and in particular the use of problem solving, allow for individualization of the program to address specific problem areas (e.g. emotional eating, restaurant eating, etc.).

Format
Behavioral programs are typically offered in a closed group format, with approximately 15–20 patients treated together in weekly sessions ranging from 16–24 weeks. Following the chronic disease model, continuation of contact is important but is gradually reduced to bi-weekly and monthly check-ins. Although longer programs have been shown to increase weight loss and delay weight regain, these time-intensive programs have been criticized as too costly and burdensome to translate and deliver outside of research settings. Recent studies have shown that phone contact can be used successfully in lieu of face-to-face contact. Likewise, providing the intervention via Internet or mobile devices can allow for more cost-effective dissemination of these programs.

OUTCOMES ACHIEVED IN BEHAVIORAL WEIGHT LOSS PROGRAMS

Weight and Health Outcomes
On average, behavioral programs produce weight losses averaging approximately 7–9 kg, with maximum weight loss typically achieved around 6–12 months. This modest weight change has been shown to facilitate meaningful improvements in cardiovascular risk factors and to reduce hypertension and hyperlipidemia and the incidence of type 2 diabetes. For example, in the Diabetes Prevention Program, the lifestyle intervention produced a mean weight loss of 7% at 6 months and 4.9% at 3 years. These modest weight losses were successful in reducing the risk of developing diabetes by 58% relative to a control group. In Look AHEAD, a study of 5,000 individuals with type 2 diabetes, those assigned to the lifestyle intervention had greater improvements in sleep apnea, kidney disease, urinary incontinence, depression, number of hospitalizations and medications. However, there were no significant differences between the intervention and control group on the incidence of cardiovascular morbidity and mortality. The benefits of weight loss are not limited to medical morbidity but also include psychological benefits such as reduced depressive and anxiety symptoms, increased self-esteem, improved body image and quality of life.

Variability in weight loss outcomes
There is marked variability in weight loss outcomes in behavioral programs, with the standard deviation for weight loss as large as the mean. Thus, some individuals do well whereas others lose little or even gain weight during treatment. It remains a challenge to identify pre-treatment indicators of success or to determine who may be at risk for poor results. Countless baseline predictors have been studied over the past two to three decades but few have proven to be reliable indicators of treatment outcome. The single best predictor of successful weight loss is adherence to regular self-monitoring of dietary intake. Because dietary changes are an essential target of treatment in order to alter an individual’s energy balance in favor of weight loss, careful attention to food intake through tracking is thought to facilitate adherence to caloric goals. Additionally, early response to treatment, defined by the weight loss observed within the first month of treatment, has been associated with the likelihood of achieving 10% weight loss after one year of treatment.

Weight maintenance
Among those who lose weight, weight regain occurs commonly in the months following weight loss treatment. This weight regain occurs in part due to physiological adaptations to weight loss (which predispose to weight regain) and to the obesogenic environment (broadly defined as micro- and macro-level features of the environment that promote inactivity and overconsumption), which makes it challenging to sustain healthy changes in eating and activity long-term. A major objective of obesity researchers is to better understand how and why weight regain occurs, who is at risk, and how to enhance maintenance over time. The National Weight Control Registry, established by Hill and Wing, includes over 10,000 individuals who lost 30 pounds or greater and maintained the weight loss for at least one year. It was developed to provide empirical support for the notion that weight maintenance is possible and to better understand factors that impact long-term weight control. Perhaps unsurprisingly, individuals who continue to adhere to a low calorie/low fat diet, engage in regular exercise, and self-monitor their weight are more likely to maintain weight loss over time. In fact, regular exercise is one of the strongest and most reliable predictors of long-term weight control following weight loss. However, it is not clear how to promote long-term adherence to these behaviors, and there have been only a few randomized trials which have successfully improved the maintenance of weight loss.
PHARMACEUTICAL ADJUVANT THERAPY
A number of anti-obesity drugs are available to assist with weight loss; these agents are reviewed in a separate contribution in this issue (Obesity Epidemic: Pharmaceutical weight loss – Stephanie A. Curry, MD). Current guidelines recommend using these medications in combination with intensive lifestyle intervention to augment weight loss outcomes. This combination produces greater mean weight loss and greater likelihood of achieving 5% weight loss compared to use of either medication or lifestyle intervention alone. Anti-obesity drugs have also been explored as a ‘rescue strategy’, with the medication prescribed when an individual fails to achieve significant weight loss or starts to regain. This approach has received minimal research attention but preliminary data indicate no benefit of implementing anti-obesity medication treatment to rescue non-responders. Conversely, more promising empirical support has been found for the introduction of pharmaceutical treatments following successful weight loss during behavioral treatment. When administered to individuals who lost at least 5% of their body weight during intensive lifestyle intervention, anti-obesity medication was associated with greater likelihood of maintaining initial weight loss as well as continued weight loss compared to a placebo control condition. As maintenance of weight loss following behavioral treatment continues to be a major clinical concern, these preliminary findings are encouraging and require further evaluation.

BARIATRIC SURGERY
Bariatric surgery is described in detail in another article in this issue (Diabetes, obesity, and other medical diseases – is surgery the answer? – Dieter Pohl, MD, FACS, FASMB; Aaron Bloomenthal, MD, FACS). While bariatric surgical procedures generally produce weight losses that are far superior and more durable than behavioral or pharmacological weight loss treatments, most patients begin to experience weight regain as early as after the initial postoperative year. Importantly, bariatric surgery is not an obesity cure, but another tool patients may use in combination with behavioral changes to achieve weight loss and related health improvements. To be most successful after bariatric surgery, patients must make multiple behavior changes such as consuming small meals/snacks (≤ 8 oz), ≥ 5 meals/snacks each day, eating slowly, stopping at satiation, and avoiding alcohol and concentrated sweets/snacks. Although surgical outcomes are enhanced when combined with changes in diet, activity, and other weight-related (e.g., self-weighing) behaviors, development and testing of behavioral interventions for bariatric surgery patients has received limited attention. Our group recently tested a behavioral intervention to increase moderate-intensity walking before bariatric surgery, as prior studies have shown that higher physical activity levels before surgery are related to greater physical activity levels and weight loss after surgery. Our intervention employed standard behavioral strategies (e.g., self-monitoring, goal-setting) to help patients increase their physical activity in bouts ≥ 10 minutes. Patients in the intervention group increased objectively-monitored moderate to vigorous physical activity in bouts ≥ 10 minutes by nearly 5-fold (from 4.4 to 21.0 min/d) where patients randomly assigned to standard care did not change (from 7.9 to 7.6 min/d). Additionally, in those patients who went on to have bariatric surgery, those who had received the intervention maintained higher physical activity levels through 6-months post-surgery compared to those in the control condition. Other recent randomized controlled trials showed that patients who received dietary counseling or were given a structured dietary intervention incorporating portion-controlled foods after surgery achieved better results than those given standard care. Research on the role of adjunctive behavioral interventions in bariatric surgery is in its infancy and critical questions regarding appropriate timing, intensity, duration, and content need to be answered.

CONCLUSION
Changing behavior is critical to weight loss success. Comprehensive behavioral interventions that help patients change their eating and exercise behaviors produce weight losses of 5–10% of body weight and clinically significant improvements in health. Such behavioral approaches are important as a stand-alone approach to weight loss as well as a key component of pharmacologic therapy or surgical approaches to weight control.

References


Authors
KayLoni Olson, MA, Weight Control and Diabetes Research Center, The Miriam Hospital, Providence, RI.
Dale Bond, PhD, Weight Control and Diabetes Research Center, The Miriam Hospital, Providence, RI, Associate Professor of Psychiatry and Human Behavior [Research], Warren Alpert Medical School of Brown University.
Rena R. Wing, PhD, Director, Weight Control and Diabetes Research Center, The Miriam Hospital, Providence, RI, Professor of Psychiatry and Human Behavior, Warren Alpert Medical School of Brown University.

Correspondence
Rena R. Wing, PhD,
Director, Weight Control and Diabetes Research Center
196 Richmond St., Providence RI 02903
401-793-8959
Fax 401-793-8944
RWing@Lifespan.org
Rena_Wing_PhD@brown.edu
In 2013, the American Medical Association (AMA) declared obesity a disease, despite the opposing recommendation of its own Council on Scientific Affairs (1). The commentaries stemming from the AMA’s decision have highlighted how difficult it is for providers to respond to what is now regularly called an epidemic of obesity. We provide a population health context for the medical approaches discussed in the other contributions to this special issue.

Despite a “health at all sizes” paradigm that argues anti-obesity campaigns have been driven by moral panic and the weight loss industries rather than actual health risks associated with obesity (2, 3), this “myth of healthy obesity” has been effectively debunked by much evidence showing that obesity does indeed increase the risk of cardiovascular events, diabetes, joint problems, apnea and some forms of cancer – in addition to its social and economic consequences. While pharmacological and surgical interventions may certainly benefit some individuals, they are not a solution for the underlying causes of the nearly three-fold increase in obesity in one generation. In Rhode Island (RI), this translates to an estimated 201,400 adults with a body mass index (BMI) indicating obesity and another 94,400 at the high end of the overweight bracket (BMI 28-30 kg/m²), in a state where the total population is barely over 1 million.

THE WEIGHT OF RI

In the past 15 years alone, obesity trends in RI reveal the extent to which unhealthy weight has become a mainstream issue. The RI Behavioral Risk Factor Surveillance System (RI BRFSS) survey is the state’s largest source of information on the health status and behaviors of RI adults. We pooled 2011-15 data to assess the most recent prevalence and distribution of obesity and severe obesity, compared to RI adults 15 years ago (pooled 1997-2000 data; full descriptions of the survey data and methodology are available from the authors, along with additional data).

In keeping with national trends, the prevalence of obesity continued its generation-long rise in RI during this period. However, a comparison across race/ethnicity and educational attainment shows that the protective effect of traditional social advantage (4) may be declining: obesity rates grew much more rapidly among non-Hispanic whites relative to non-Hispanic blacks [Table 1a, Figure 1a] and among adults with higher levels of education compared to adults without a high school degree [Table 1b, Figure 1b]. At the same time, rates have risen almost as much among Hispanic/Latino adults; while this, too, might reflect the same trends of relative social advantage (health behaviors have been shown to worsen with acculturation and its accompanying improved access to healthcare) (5), different sociocultural trajectories may be driving different populations to statistical parity.

Many explanations for the overall rise in obesity have been suggested, but changes leading to increased energy consumption and decreased activity are clearly the main drivers. We draw attention to two findings in particular. First, Hill et al. calculated that very incremental energy accumulations – a median 15 kcal/day – were driving U.S. weight gain (6). Second, Kranjac and Wagmiller found both a cohort and an intracohort effect – i.e., not only the changing demographic composition of more recent population cohorts and changing behaviors across all cohorts are accounting for the collective weight gain (7).

At the same time, it is important that providers be alert to the possibility of mental distress underlying weight gain, as it has been found to underlie the rising white mortality rate (8). Compared to people with a BMI below the obesity

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Table 1a. Prevalence of weight categories among RI adults in 1997–2000 and 2011–2015, by race/ethnicity

<table>
<thead>
<tr>
<th>Weight Category</th>
<th>white (non-Hispanic)</th>
<th>black (non-Hispanic)</th>
<th>Hispanic/Latino</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal weight (BMI &gt;18.5 &amp; &lt;30)</td>
<td>45.3 (42.4-46.5)</td>
<td>35.8 (34.9-36.6)</td>
<td>33.0 (27.1-38.8)</td>
</tr>
<tr>
<td>Overweight (BMI 25-29.99)</td>
<td>36.9 (35.8-38.0)</td>
<td>36.8 (36.0-37.7)</td>
<td>36.5 (30.7-42.3)</td>
</tr>
<tr>
<td>Class 1 obesity (BMI 30-34.99)</td>
<td>11.5 (10.8-12.3)</td>
<td>16.4 (15.7-17.0)</td>
<td>18.5 (13.9-23.0)</td>
</tr>
<tr>
<td>Class 2 obesity (BMI&gt;35)</td>
<td>4.1 (3.7-4.6)</td>
<td>9.6 (9.1-10.1)</td>
<td>10.6 (6.9-14.3)</td>
</tr>
</tbody>
</table>

Data source: RI Behavioral Risk Factor Surveillance System
Table 1B. Prevalence of weight categories among RI adults in 1997–2000 and 2011–2015, by educational attainment

<table>
<thead>
<tr>
<th>No high school degree</th>
<th>High school degree/GED</th>
<th>1-3 years of post-secondary education</th>
<th>4+ years of post-secondary education</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal weight (BMI &gt;18.5 &amp; &lt;30)</td>
<td>35.3 (32.4-38.2)</td>
<td>33.0 (30.3-35.6)</td>
<td>44.9 (43.0-46.8)</td>
</tr>
<tr>
<td>Overweight (BMI 25-29.99)</td>
<td>39.9 (36.9-42.9)</td>
<td>35.4 (32.9-38.0)</td>
<td>37.2 (35.3-39.0)</td>
</tr>
<tr>
<td>Class 1 obesity (BMI 30-34.99)</td>
<td>18.4 (16.1-20.7)</td>
<td>17.7 (15.8-19.7)</td>
<td>12.8 (11.5-14.1)</td>
</tr>
<tr>
<td>Class 2 obesity (BMI&gt;=35)</td>
<td>6.3 (4.9-7.8)</td>
<td>12.4 (10.7-14.1)</td>
<td>5.1 (4.3-5.9)</td>
</tr>
</tbody>
</table>

Data source: RI Behavioral Risk Factor Surveillance System

threshold, obese adults in 2015 were more likely to report multiple days of poor mental health in the past month or past/current depression ([Figure 2]). BRFSS does not provide other measures of mental distress, nor the use of atypicals and antidepressants, both of which carry the risk of serious weight gain. A medical-public health framework also needs to find a way to address the associations between high BMI and anxiety over affording nutritious meals and rent/mortgage, as this may be the kind of stress for which people turn to constant energy-dense but low-nutrition snacks as a coping mechanism ([Figure 2]; additional data available on request).

**WHAT CAN RI PROVIDERS DO?**

Given the scale and drivers of the obesity epidemic, RI providers might feel there is little they can do – or even that the responsibility does not rest with them. Despite the increased prevalence of obesity, several studies have found that providers are even less likely to counsel their patients about weight than they used to [9]. Providers can’t bear sole responsibility for helping their unhealthy-weight patients lose weight, but they do have a critical role to play. While acknowledging the very real barriers such as competing demands on limited consultation time, discomfort with starting a sensitive conversation, and frustration with patient failure to progress, we suggest several public health approaches for providers to consider.
• Screen and intervene before BMI hits 30, as well as after
Weight loss is difficult to both achieve and sustain once people have become obese, and in this as in every public health problem, prevention is the best solution. Although the overweight adult population as a whole has remained relatively stable (above 1 in 3 adults), providers should be especially concerned about the rising percentage in the “red zone” (BMI 28-30, or just below the obesity line).

• Refer patients to lifestyle change programs
Much of the medical literature on obesity is driven by genetics research and pharmacological interventions. But sustained reliance on pharmacological approaches, with all their attendant side effects and price tags, is not a solution to so widespread a health problem. The RI Department of Health (RIDOH) provides a centralized location (the Community Health Network) where providers can refer patients with or at risk of chronic disease to free lifestyle modification classes that teach patients how to develop healthier habits; providers simply submit a referral form and a RIDOH patient navigator contacts the patient to help them enroll in a class. Providers are then sent updates on their patients’ enrollment status. Providers can make arrangements by emailing DOH.Community@health.ri.gov or calling (401) 222-3600. Patients can also view and register for programs at http://www.health.ri.gov/find/communityhealthnetworkprograms/. However, multiple studies have found that patient engagement is higher with provider involvement in the process.

• Work with a Community Health Worker (CHW) to help patients with life’s challenges
Most providers know that simply telling their patients to lose weight and sending them on their way is unlikely to be effective. As Figure 2 reminds, obese patients may face complex challenges involving not only long ingrained habits but socioeconomic barriers: they may struggle to find time and money, to shop for and prepare fresh produce, or they may be using unhealthy behaviors as coping mechanisms to deal with stress or anxiety. While the RI Medical-Legal Partnership can help with some legal problems (e.g., delinquent landlords), medical practices are increasingly finding that CHWs can help with both psychosocial and logistical challenges outside the clinical setting through such things as helping patients apply for the Supplemental Nutrition Assistance Program (SNAP), providing informal counseling and social support, or ensuring patients with low health literacy understand the information or materials they were given.

• Invest in communication
Weight can be a difficult topic to broach with patients. With RI’s increasingly diverse population, it is especially important to understand the social and cultural conflicts that can arise despite the best of intentions [10]. CLAS (culturally and linguistically appropriate services) resources like https://www.thinkculturalhealth.nih.gov/education/physicians and https://www.niddk.nih.gov/health-information/health-topics/weight-control/talking-with-patients-about-weight-loss-tips-for-primary-care/Pages/talking.aspx can provide helpful tips.

• See your patients in a population-health perspective
The individual patients in front of you are above all your individual patients: but we hope that remembering the extent of health-imperiling weight in RI – not least the doubling of class 2 obesity as reflected in Table 1b – will encourage providers to work together with the public health sector toward primary as well as secondary prevention.

Like quitting smoking, losing weight is hard and may require multiple attempts. But providers can make it easier for their patients to succeed if they provide not only medical treatment for the individual, but professional and civic partnership on public policies that facilitate choosing healthier options throughout the day.

References

Authors
Dora M. Dumont, PhD, MPH, is Senior Public Health Epidemiologist, Division of Community Health and Equity, RI Department of Health.
Kristi A. Paiva, MPH, is Public Health Evaluator, Division of Community Health and Equity, RI Department of Health.
Eliza Lawson, MPH, is Health Program Administrator, Division of Community Health and Equity, RI Department of Health.

Correspondence
Dora M. Dumont, PhD, MPH
Senior Public Health Epidemiologist
Division of Community Health & Equity
Rhode Island Department of Health
3 Capitol Hill, Providence, RI 02098
401-222-4804 dora.dumont@health.ri.gov
Quality Improvement Processes in Obesity Surgery Lead to Higher Quality and Value, Lower Costs

HOLLI BROUSSEAU, AGACNP; DIETER POHL, MD, FACS, FASMBS

ABSTRACT
In the era of changes in the evaluation of medical services and performance, the Centers for Medicare and Medicaid Services (CMS) has determined that the key components are quality, value, and clinical practice improvement (MACRA). Weight Loss Surgery, also called Bariatric or Obesity Surgery, has been at the forefront of quality improvement and quality reporting through the Center of Excellence Program since 2005. As a result, weight loss surgery is now as safe as gallbladder surgery. Even within this culture of quality and safety, improvements are still possible, as described in this article.

KEYWORDS: bariatric surgery, quality improvement, readmissions, MACRA, ACS

INTRODUCTION
Quality project D.R.O.P.: Decreasing Readmissions through Opportunities Provided
The American College of Surgeons (ACS) provides several quality improvement programs, for surgery in general, and for surgery in specialties such as bariatric, breast, cancer, pediatric, and trauma. These programs contract with Medicare and are Qualified Clinical Data Registries (QCDR), and participation in these programs automatically fulfills the Physician Quality Reporting System (PQRS) requirement for each participating provider.

The program for bariatric surgery is called Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). Participating hospitals in this program employ a full-time, independent chart reviewer who records an extensive list of perioperative and operative data in a national database.

Roger Williams Medical Center (RWMC) is a MBSAQIP Accredited-Comprehensive Center. In 2015 RWMC participated in a national pilot project called D.R.O.P: Decreasing Readmissions through Opportunities Provided. It was an opportunity for RWMC to improve patient care, quality and value by implementing several measures to decrease readmissions.

METHODS
The study period was March 1, 2015–March 31, 2016 and was compared to 2014. Data were collected for all readmissions within 30 days post-op, reason for readmission, and length of stay of a readmission. The hypothesis was that the intervention D.R.O.P. would decrease the number of readmissions. Other questions of interest were to see if the cause of readmissions would change and whether there was a correlation between length of stay and reason for readmission.

The project included implementing the pre-operative handout of the narcotic pain management prescription to patients’ family members in order to avoid any issues at the pharmacy on the day of discharge. The patients were discharged with improved verbal and written education about post-op hydration, nausea and vomiting, pain management, and they were given a business card-like information card, the “Bariatric Help” card, with emergency numbers, as well as the physician’s office number. The physician or bariatric coordinator called the patients within 24 hours post discharge. The call was made with the purpose to speak directly to the patient and assess their status at home by asking them the predetermined questions for the quality project. The nine questions included: Is there someone to care for you at home, hydration status and tolerance of oral intake, pain managed with their medicine, have they started taking their vitamins, do they have the bariatric help card with the phone numbers they would need, questions about surgical incision redness or swelling, bowel movement, walking 3 or 4 times a day, and do they have their follow-up appointment with a dietitian within 30 days. Depending on the individual patient’s answers any issues could be triaged while they were at home and on the phone. The patients often needed some re-education on the phone call about hydration and its importance.

RESULTS
In 2014, RWMC did 310 bariatric surgeries with a total number of 23 readmissions (7.42%). Of those, 232 were Laparoscopic Roux-En-Y Gastric Bypass surgeries with 19 readmissions (8.9%) and 78 Laparoscopic Sleeve Gastrectomy surgeries with 4 readmissions (5.13%).

In 2015/2016, the study period, RWMC did 390 surgeries with 12 readmissions (3.08%). Of those, 291 were
Laparoscopic Roux-En-Y Gastric Bypass procedures with 8 readmissions (2.75%) and 94 Laparoscopic Sleeve Gastrectomy surgeries with 4 readmissions (4.26%).

Less than 24-hour hospital stay readmissions occurred for 8 out of 310 patients [2.5%] in 2014, compared to 0 patients in the study period.

For the hospital stay 24–48 hours there were 8 readmissions for 310 patients [2.5%] in 2014, compared to 5 patients out of 390 (1.2%) in the study period.

For the hospital stay greater than 48 hours there were 8 readmissions (2.5%), compared to 8 readmissions for 390 patients (2%) in the study period.

Looking at the reasons for readmissions in 2014, 6 out of 310 patients (1.9%) were classified as “Other” whereas in the study period 2015/16, it was 4 out of 390 patients (1%). “Nausea, Vomiting, and Dehydration” etc. occurred in 2014 in 4/310 patients (1.3%) and in 2015/16 it was in 6/390 patients (1.5%). More serious complications such as bleeding, leak, intestinal obstruction or sepsis did not occur in the study period.

**INTERPRETATION**

**Readmissions**

The rate of readmission decreased from 7.4% to 3%. This was primarily achieved by decreasing overall complication rates in laparoscopic gastric bypass and by decreasing the readmissions that required only short stays in the hospital. Stays less than 24 hours were completely eliminated. Stays 24–48 hours went from 2.5% to 1.2%. Because the longer hospital stays and the nausea/vomiting category stayed the same, one can deduce that patients who stayed longer had more serious cases of nausea/vomiting/dehydration. The classification of more non-specific reasons in the “Other” category improved which made the data from the study period more specific.

According to CMS, in the new healthcare delivery system reform and Medicare payment reform, quality encompasses the major determinant of compliance. Included in quality is the former value modifier. One of the value modifiers is all-cause readmission, which, according to patient understanding, physician perception, hospital quality departments, CMS and all commercial insurers, is seen as a complication.
Readmission is also one of the quality measures in the proprietary Center of Excellence and value programs of all commercial insurance companies. Reducing readmission improves those quality and value measures.

Although cost was not measured in this study, The Agency for Healthcare Research and Quality reported that in 2011 all-cause readmission for all medical conditions cost hospitals $41.3 billion. Besides the patient care quality improvement, another major benefit of reduced readmissions would therefore be reduced hospital and health care cost.

**SUMMARY**

The premise of MACRA is that patient care and reimbursement will be tied more to quality, value, and improvement programs. Participation in one of the many quality improvement programs of national professional organizations such as the American College of Surgeons can enable physicians and institutions to reach these goals – for their own, their patients and society’s benefits.

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**Authors**

Holli Brousseau, AGACNP, Bariatric Coordinator, Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) Accredited-Comprehensive Center; CharterCARE Medical Associates, Roger Williams Medical Center, Department of Surgery, Providence, RI.

Dieter Pohl, MD, FACS, FASMBS, Director, Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) Accredited-Comprehensive Center; Division Director, General Surgery, CharterCARE Medical Associates, Roger Williams Medical Center, Department of Surgery, Providence, RI.

**Disclosures**

None

**Correspondence**

Dieter Pohl, MD
1539 Atwood Ave.
Johnston, RI 02919
401-521-6310