Bariatric Surgery in New Jersey, 2005

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Executive Summary

The recent rapid increase in the volume of bariatric surgery, coupled with several well-publicized cases of serious complications or death following the surgery, and a lack of information specific to bariatric surgery in New Jersey was cause for concern for the New Jersey Department of Health and Senior Services (Department) to monitor bariatric surgeries trends and their outcomes. In October 2005 the Department released its first report on bariatric surgeries performed in New Jersey using the 2003 Uniform Billing (UB) data. The first report was mainly based on discussions and recommendations of the work group formed by the Department to make a baseline assessment of the prevalence of bariatric surgery in the State. This report, compiled by the Department, is a continuation of the first report and uses 2005 UB data on bariatric surgeries.

Interventions that reduce overweight and obesity range from behavioral modification, such as dieting and increased physical activity, to the use of medications and bariatric surgery. The short- and long-term effectiveness of each approach differs for each intervention. More importantly, even medications and surgical interventions require behavioral modifications, such as physical activity and dieting, to be effective weight reduction strategies.

It is generally accepted that about 20 kilograms (over 40 pounds) can be lost as a result of bariatric surgery with the additional benefits being lower risk for diabetes, hypertension, cardiovascular disease, and certain cancers. However, bariatric surgery is a medical procedure that can result in serious medical problems including complications and death. Also, the lack of detailed practice guidelines for bariatric surgery by any national certifying boards makes it difficult to evaluate best surgical practices. As a result, any report which is based on secondary data must be used with caution.

Despite its limitations, this report provides useful information on bariatric surgery in general, including its benefits and risks as well as the extent it is practiced in New Jersey. In particular, the report presents variations of the State bariatric surgery population by gender, age and health insurance status while documenting important outcomes.

These are the key major findings of the report:

- In 2005, 22.1% (or 1,448,849) of adults were obese and 37.1% (or 2,432,231) were overweight, according to the Behavioral Risk Factor Surveillance System (BRFSS).

- There were 4,451 bariatric surgeries in New Jersey in 2005, which suggests a modest (3.3%) decline from the 2004 level of 4,605.

- Bariatric surgery appears to have stabilized at around 4,500 surgeries a year, suggesting a possible maturing of the practice in the state.

- Consistent with previous years, 79% of bariatric surgery patients were women.

- Most bariatric surgery patients (71.5%) were 30-54 years old with 13.3% between the ages of 15 and 29.

- Most bariatric surgery patients (86.5%) had private insurance, 6.1% had Medicare and Medicaid accounted for less than 1%. The remaining 6.8% was accounted for by self-pay (2.2%) and others (4.6%).

- High volume hospitals tended to have lower readmission rates and lower 30-day mortality rates, while low volume hospitals had higher readmission rates and higher mortality rates.

- Surgeon volume was inversely related to both 30-day mortality rate and bariatric surgery complication rate 180 days post-surgery.

- Volume, which is used as a surrogate for experience in performing bariatric surgery procedures, appears to be vital for positive outcomes.

- The average hospital length of stay for a bariatric surgery patient was 3.2 days. Hospital stays ranged from 1.3 days to 8.8 days.

- In 2005, total statewide hospital charges amounted to $186 million. Hospitals collected only about $46 million (about $10,000 per patient) for their services.

Introduction

In October 2005 the Department of Health and Senior Services (Department) released a report on bariatric surgeries performed in New Jersey using 2003 data. The report was mainly based on discussions and recommendations of a work group formed by the Department to assess bariatric surgery prevalence in the State. The Bariatric Work Group was comprised of bariatric surgeons, representatives of providers and payers, medical directors of managed care plans, health care consultants, and consumer advocates. The recent rapid increase in the volume of bariatric surgery, coupled with several well-publicized cases of serious complications or death following the surgery, and a lack of information specific to bariatric surgery in New Jersey was cause for alarm for the Department to form the Work Group and conduct the study.

The Work Group discussed the following issues in detail:

- What data are currently available on bariatric surgery in NJ, and are these data adequate for needs enhancement?
- What are the appropriate indications of medical necessity for various types of bariatric surgery?
- What are the core elements of a good, comprehensive program?
- What are the professional competencies and training essential to a successful bariatric surgery program?
- Is there a volume/quality association for bariatric surgery?
- Are there agreed-upon standards for assessing the quality of bariatric surgery programs?
- What are the typical complications associated with bariatric surgery, and are there best practices that reduce the risks of these complications as well as mortality?

The Work Group was aware that the Uniform Billing (UB) data set is the only source of information on bariatric surgery cases in New Jersey. The Work Group reviewed efforts in Massachusetts, New York, and Pennsylvania to see how they used their UB data to study bariatric surgeries in their respective states. Moreover, the group consulted with payer representatives from among the Bariatric Work Group members to help with the diagnostic and procedure codes to use to identify bariatric patients. This process resulted in an approach that combines diagnosis codes with procedure codes (discussed later) to identify likely bariatric surgery cases within the UB data.

The Department receives an electronic copy of each claim, or bill, developed by hospitals for each inpatient admission and emergency department visit, roughly four million records per year. This Uniform Billing (UB) data base includes extensive demographic and clinical data, including one primary diagnosis code and up to eight secondary diagnosis codes (scheduled to be expanded to more than eight secondary codes in 2007), and as many as eight procedure codes.

The UB data base uses a standard format governed by the National Uniform Bill Committee. New Jersey is one of many states that collect a copy of hospital UB data for public health purposes. The UB data set is derived from patients' medical charts, but, since its primary purpose is to collect payments from insurers and other payers, it does not always contain all items that may interest researchers. Additionally, since some items on the form are of less interest to insurers than to researchers, the reliability of data collected using a UB form is not uniform. Even though UB data are not audited, and have well-known limitations, their large size and ready availability have made them the most frequently used public data sets in health services research.

As part of the Work Group activities, Department staff analyzed the 2003 hospital discharge data with the aim of reviewing statewide trends in bariatric surgery and examining outcomes. The report can be found at the Department's website (http://www.nj.gov/health/healthcarequality/other.shtml). In the 2003 report, the Work Group suggested that the Department continue to use its hospital discharge data for periodic monitoring of bariatric surgery. Following their recommendation, the current report uses data on surgeries performed in 2005 to study bariatric surgery and its outcomes in New Jersey[1].

Unlike the previous report, which provided data based on the patient's discharge year, the current report uses data on 4,451 patients who had bariatric surgery in 2005 regardless of their discharge date. For example, the 4,451 bariatric surgery cases in 2005 refer to all cases admitted and discharged in 2005 plus those admitted in 2005 but discharged in 2006 (Table 2). Only 17 of the 4,451 bariatric surgery patients were admitted in 2005 but discharged in 2006. As in the previous report, we followed patients through data matching to estimate hospital length of stay, and reported complications 180 days after bariatric surgery and mortality within 30 days following surgery.

The current report also includes a summary of findings from a short survey of 36 hospitals that the 2003 UB data showed had performed bariatric surgery.

Overview

Obesity is a critical health problem that affects approximately 60 million adults in the United States (US) including about 1.4 million in New Jersey. In 2005, 22.1% of New Jersey adults (1,448,849 of 6,555,880) were considered obese while 37.1% (2,432,231 of 6,555,880) were overweight. In recent years, the prevalence of obesity has risen steadily in all states; in both sexes; across age groups, races, and educational levels; and regardless of smoking status.[1]

[1] Except for expert advice solicited from some Work Group members on updating of codes, the Work Group was not involved in the preparation of the current report.

Obesity is defined as an excessively high amount of body fat in relation to lean body mass. People become overweight and obese as a result of an imbalance in the amount of calories consumed and the amount of calories burned. Other factors that likely contribute to obesity include genetics, age, ethnicity, pregnancy history, medications, medical problems such as low thyroid function, and lack of sleep. Some people point to environmental and socioeconomic factors, such as suburban living to be associated with reduced exercise. Large portions of food consumption also contribute to increased calories.

Numerous medical conditions are related to overweight and obesity. This partial list includes high blood pressure, type-2 diabetes (insulin resistant/adult onset), high cholesterol level, coronary heart disease, gall bladder disease, asthma, sleep apnea, osteoarthritis, infertility, idiopathic intracranial hypertension, lower extremity venous stasis disease, gastroesophageal reflux, and urinary stress incontinence. Furthermore, American Cancer Society researchers have documented a strong association between obesity and many forms of cancer.[2] The report substantiates previous studies linking overweight and obesity to cancers of the colon and rectum, breast (in postmenopausal women), uterus, kidney, esophagus, and gall bladder. The report also links additional forms of cancer—stomach, liver, pancreas, prostate, non-Hodgkin lymphoma, multiple myeloma, cervical, and ovarian—to overweight and obesity.

Besides being associated with other diseases, obesity itself has been recognized as a disease since 1985 by the National Institutes of Health (NIH). In July 2004, the Centers for Medicare and Medicaid Services (CMS) removed language in the Medicare Coverage Issues Manual stating that obesity was not an illness.[3]

By some estimates, obesity is associated with approximately 26,000 to 112,000 excess deaths each year.[4] In addition to facing increased morbidity and mortality, people with obesity also suffer from social stigma and workplace discrimination. One CDC study estimates that U.S. obesity-attributable medical expenditures reached $75 billion in 2003.[5] Taxpayers financed about half of these costs through Medicare and Medicaid. With the addition of indirect costs, such as lost wages caused by obesity-related illnesses, the total amount spent as a result of obesity exceeds $100 billion per year.[6]

Factors relating a person's weight status to potential risk for disease include the following: age, height and weight, fat composition and distribution, and the presence or absence of other health problems and risk factors. The body mass index (BMI) is a measure of body fat based on a relationship between weight and height. The same BMI cut points (Table 1) can be used to classify the level of overweight and obesity for adult men, adult non-pregnant women, and generally for all racial/ethnic groups.[7] Waist circumference should also be measured, because increased abdominal fat appears to be an independent risk predictor when the BMI is not markedly increased. According to the NIH, a high waist circumference (>35 inches for women and >40 inches for men) is associated with

an increased risk for type-2 diabetes, dyslipidemia, hypertension, and cardiovascular disease (CVD) in patients with a BMI between 25 and 34.9.[8]

Table 1. Body Mass Index (BMI) Cut Points

Category	BMI
Underweight	<18.5
Normal	18.5 - 24.9
Overweight	25.0 - 29.9
Obesity Class I	30.0 - 34.9
Obesity Class II	35.0 - 39.9
Morbid Obesity Class III	≥ 40.0

Note:

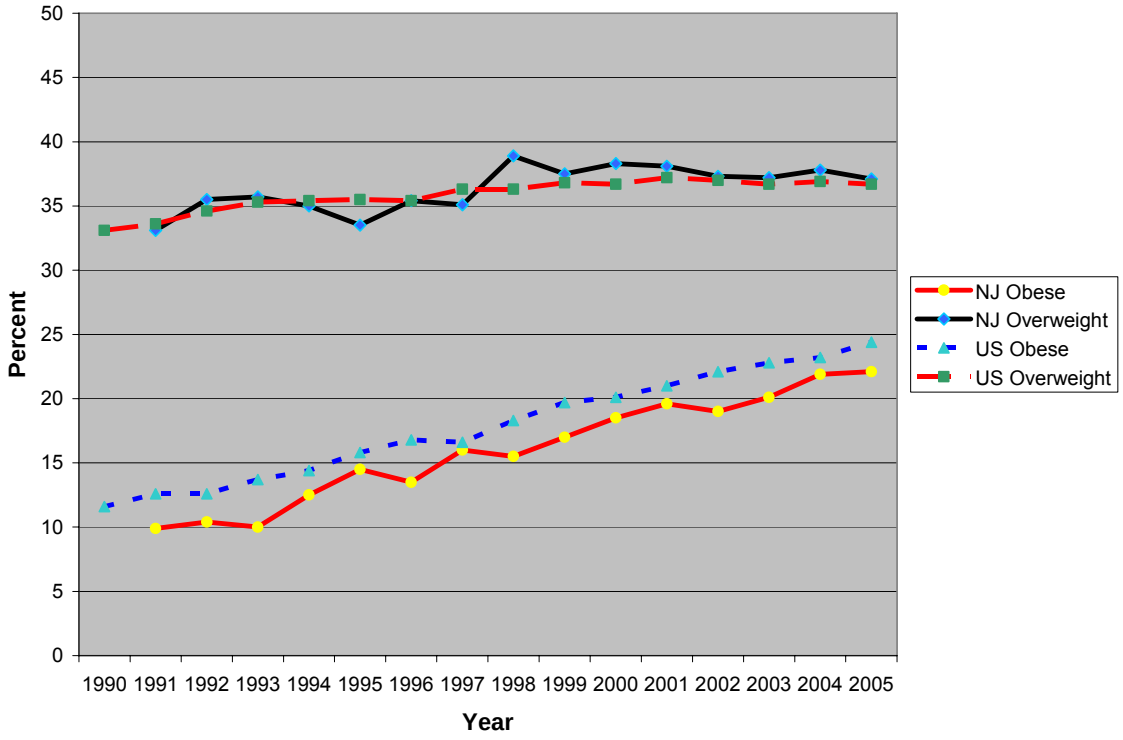
BMI = weight (kg) / [height (m)]^2, where kg = kilograms, m = meters

OR

BMI = weight (lb) / [height (in)]^2 x 703, where 703 is the conversion factor

Under the direction and with the support of the federal government, states conduct ongoing surveys of adults, the Behavioral Risk Factor Surveillance System (BRFSS), to identify the prevalence of behaviors and characteristics associated with health risks.[9] In 2005, 22.1% of New Jersey adults (1,448,849) were considered obese while 37.1% (2,432,231) were overweight. Survey findings for years 2000-2005 show that overall, the percentage of adults in New Jersey who are overweight is consistently higher than the national average. Conversely, the percentage of New Jersey's adults who are obese has been slightly lower than the percentage nationwide. In both the nation and New Jersey, the obese population has been increasing at a faster rate than the overweight population[10] (see Figure 1).

Figure 1. Trends in Overweight and Obesity: New Jersey VS. US



Notes: Overweight means BMI = 25.0-29.9, Obese means BMI ≥ 30.0
Source: CDC, Behavioral Risk Factor Surveillance System

Preventing Obesity

At any given time, about 29 percent of men and 44 percent of women in the US are attempting to lose weight. However, only 20 percent report that they are reducing calories or engaging in physical activity to achieve weight loss.[11] For those who do lose weight, maintaining weight loss over the long term is exceedingly difficult. Most people regain as much as two-thirds of weight lost within one year and regain all the weight within five years.[12]

According to the NIH, preventing obesity includes *primary prevention of overweight or obesity itself*, *secondary prevention or avoidance of weight regain following weight loss*, and *prevention of further weight increases in obese individuals unable to lose weight*.[13] The NIH also argues that preventing and treating obesity through medical and lifestyle approaches are interdependent. Bariatric surgery, for example, is most effective as a weight loss tool when patients comply with recommended preventative dietary and physical activity regimens after the surgery (See Appendix C).

Losing even a small amount of weight is beneficial for the individual's health. For example, according to the U.S. Preventive Services Task Force, weight reduction of five to seven percent of body weight is associated with lower blood pressure, improved cholesterol, and decreased risk of developing diabetes.[14]

Preventing children from becoming overweight is critical so that they do not become overweight as adults. Research shows that about one-third of overweight preschool children and one-half of overweight school age children remain overweight as adults.[15] In June 2002, the New Jersey Childhood Obesity Roundtable was convened by the Department to determine the extent of the youth obesity problem in the state. The group found that while 60 percent of sixth graders in New Jersey were of normal weight, eighteen percent were overweight and another twenty percent were obese.[16] It is essential that children and their parents learn about the extent of the overweight problem and practice obesity prevention measures throughout the lifespan.

Recognizing the extent of the obesity problem, the State of New Jersey established by law (P.L. 2004, Chapter 303) an Obesity Prevention Task Force in the Department.[17] The task force consisted of 27 members, including the Commissioners of Health and Senior Services, Human Services, and Education; the Secretary of Agriculture; and a wide range of expert stakeholders. The task force was charged with developing a statewide Obesity Action Plan, which includes recommendations for specific actionable measures to support and enhance obesity prevention among State residents, particularly children and adolescents.

The *Obesity Prevention Action Plan* was published in the summer of 2006. There is a national consensus, the report notes, on the five key areas of intervention to reverse the obesity epidemic – improved nutrition, increased fruit and vegetable consumption, increased physical activity, exclusive breastfeeding of infants, and decreased "screen time" including television viewing, computer use and video games. The report is comprehensive and addresses all aspects of obesity prevention from seven major themes; infrastructure, public/professional awareness, communities, schools, workplace, health care system, and disparities.

The Task Force considered each of these areas in outlining a series of goals, strategies and action steps. The report calls for actions on the part of federal, state and local government; local organizations and neighborhoods; public and non-public schools; workplaces; and healthcare systems and health professionals. All parts of the community must work together to support healthy behaviors that can help reduce obesity, according to the report.

The full report, with an extensive set of strategies and action steps, can be viewed on the department's web site at www.nj.gov/health.

Types of Bariatric Surgery

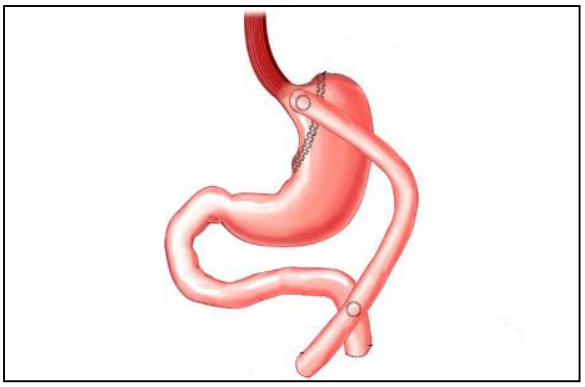
Interventions for reducing overweight and obesity range from dieting, increasing physical activity and other behavior modification, to medications and bariatric surgery. Research shows that short- and long-term effectiveness differs for each intervention. Furthermore, even pharmaceutical and surgical interventions require a combination of physical activity, diet, and behavioral intervention to be optimally effective.

As the percentage of overweight and obese New Jerseyans has risen, so too has the volume of surgical treatments for obesity. According to clinical guidelines developed by the National Heart, Lung, and Blood Institute (NHLBI) Expert Panel, ***surgical intervention is recommended only for those with BMI > 40 or BMI of 35 to 40 with at least one obesity-related co-morbidity***. This suggests that not all obese individuals should be provided with bariatric surgery as an option for their overweight problems.

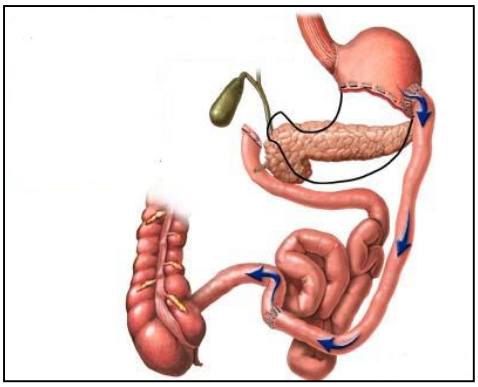
There were 44,937 cases in the New Jersey 2005 UB data diagnosed with obesity (27,130 cases of ICD-9-CM = 278) or morbid obesity (17,807 cases of ICD-9-CM = 278.01). Of the morbidly obese (17,807 cases), only 25.0% (4,451 cases) had bariatric surgeries. Of the 4,451 bariatric surgery cases, only 23 (0.5%) were not morbidly obese cases. This shows the consistency with the NHLB guidelines stated above. Appendix C presents more details on prevention and treatment approaches which was also presented fully in the first report.

Bariatric surgery is performed by using laparoscopic procedures or by laparotomy (open procedures). Such surgeries are either restrictive, malabsorptive, or both. Restrictive procedures limit the flow of food through the digestive tract by closing off part of the stomach and limiting the amount of food that can be held in the stomach at one time. Malabsorptive procedures prevent food from being fully absorbed in the intestine. All types of bariatric surgery require follow-up commitment to diet and lifestyle changes, as well as ongoing use of nutritional supplements, in order to maintain weight loss and avoid adverse health consequences related to malabsorption. The major types of bariatric surgery are as follows:

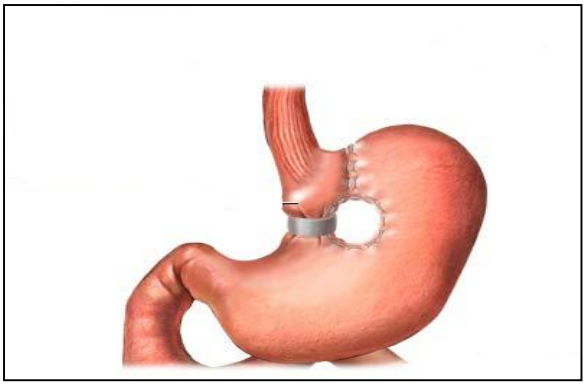
(1) **Roux-en-Y Bariatric (RYGB),** the most commonly performed weight loss surgery in the United States, has both restrictive and malabsorptive components. This procedure creates a small pouch from the original stomach. The pouch remains attached at one end to the lower part of the esophagus and, at the other end, there is a new connection created to a section of small intestine, thus bypassing the remaining part of the stomach and the initial loop of small intestine (see diagram). Patients who undergo RYGB are at risk for developing various nutritional deficiencies along with the desired loss of weight. They must take lifelong supplements of multivitamins, vitamin B12, iron, and calcium. They also require long-term follow-up for physical, nutritional, and metabolic evaluation and counseling.



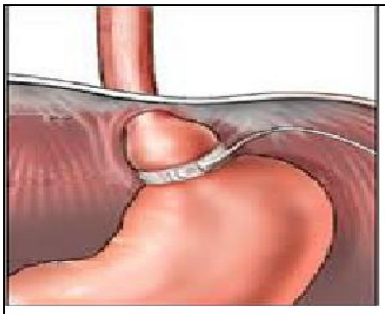
(2) **Biliopancreatic Diversion (BPD)** is a malabsorptive operation in which portions of the stomach are removed. The small pouch that remains is connected to the final segment of the small intestine which completely bypasses the first two sections of small intestine. This procedure is used less frequently than others because of the high risk of nutritional deficiencies that accompany weight loss. For patients who undergo BPD, long-term nutritional supplementation, biochemical monitoring, and clinical follow-up are absolutely essential.



(3) **Vertical Banded Gastroplasty (VBG)** restricts volume intake, but has no malabsorptive effect. Staples are used to create an artificial pouch in one section of the stomach. The band connects the small upper pouch with the larger part of the stomach which is below the band. The band connecting the two parts creates a small outlet. Food passes slowly through the outlet from the pouch to the lower part of the stomach. With adjustable VBG, the diameter of the outlet can be changed to allow smaller or larger amounts of food to pass. Patients must be instructed to chew well and eat slowly. Failure to do so may result in repeated vomiting and isolated cases of protein and vitamin deficiency. Careful patient follow-up is mandatory.



(4) **Laparoscopic Adjustable Gastric Banding (LAGB)**, introduced to the U.S. market in 2001, has become increasingly popular. In LAGB, an adjustable silicone band is placed around the upper stomach to create a small pouch and a restricted outlet. The diameter of the outlet can be changed by injecting or removing saline through a portal under the skin. Patient compliance and follow-up is similar to that required for VBG patients. If the LAGB is not effective, or if serious complications develop, the band can be removed.



Potential Outcomes of Bariatric Surgery

Weight reduction obtained with surgical intervention is typically 20 kilograms or more. The benefits of bariatric surgery include the reduction of risk factors for co-morbidities such as diabetes, hypertension, cardiovascular disease, and certain cancers. In addition, many patients report that post surgery they enjoy enhanced quality of life; improved mobility and stamina; better mood, self-esteem and interpersonal effectiveness; and lessened self-consciousness.

Using a statistical approach known as meta analysis, Maggard et al. argue that the relationship between bariatric surgery and complication rates is complex and the direction of the relationship is inconclusive.[18]

Despite the growing interest in bariatric surgery outcomes, there is no national reporting and classification system regarding the complications of bariatric surgery and caution must be exercised in using such data at face value. According to Buchwald complication rates were difficult to catalog because of inconsistent reporting of data, dependence on length of follow-up and other factors"[19] .

Finally, the risk of mortality or complications is greater with increased weight or BMI, male gender, increased age, and revisional surgery (revisional surgery is performed on those who have already had a bariatric procedure and require some type of surgical repair). In particular, patients older than 50 years who have a BMI > 50 appear to have a significantly elevated risk. Severe medical conditions that may contribute to increased risk include type-2 diabetes, hypertension, and obstructive sleep apnea.[20]

While severe medical conditions may increase the risk of complications, bariatric surgery may help resolve or significantly mitigate some of these same co-morbidities. Buchwald et al. documented a strong evidence for the improvement of type-2 diabetes and impaired glucose intolerance following bariatric surgery. Their findings also suggest that hyperlipidemia, hypertension, and obstructive sleep apnea were also significantly improved following bariatric surgery.[21]

The lack of detailed practice guidelines for bariatric surgery by any national certifying boards makes it difficult to evaluate best surgical practices.

Identifying Bariatric Surgery Cases in the UB Database

Two diagnosis codes and a number of procedure codes were identified as indicators of a bariatric surgery case from the UB data. The decision to use these codes was made by experts in bariatric surgery as well as payer representatives

of the Work Group. The list of the ICD-9-CM diagnosis and procedure codes is given below. This list includes recent additions of procedure codes 44.38, 44.68, 44.95, 44.96, and 44.97 per the Generic ICD-9-CM coding manual (Volumes, 1, 2, 3; 2007). These additions were verified by some Work Group members for relevance.

Diagnosis Code	Procedure Code
278 - Obesity and other hyperalimentation **278.01** - Morbid obesity	**43.7** - Partial gastrectomy with anastomosis to jejunum **43.89** - Other partial gastrectomy **44.31** - High gastric bypass **44.38** - Laparoscopic gastroenterostomy **44.39** - Other gastroenterostomy **44.68** - Laparoscopic gastroplasty **44.69** - Repair stomach NOS **44.95** - Laparoscopic gastric restrictive procedure (band/pot insertion) **44.96** - Laparoscopic revision of gastric restrictive procedure **44.97** - Laparoscopic removal of gastric restrictive device(s) **45.91** - Small to small intestinal anastomosis

In order for a patient to be eligible for the bariatric surgery analysis, he/she had to have been diagnosed as morbidly obese (ICD-9-CM = 278.01) or as having obesity and other hyperalimentation (ICD-9-CM = 278), and had to have had at least one of the procedures performed from among the list above.

There were 17,807 morbidly obese cases (ICD-9-CM = 278.01) and 27,130 obese with hyperalimentation cases (ICD-9-CM = 278) in the 2005 New Jersey UB data. Of the morbidly obese cases, only 25.0% (4,451 cases) had bariatric surgeries.

Trends in Bariatric Surgery in New Jersey: 1998 - 2005

Bariatric surgery in New Jersey has shown a sharp increase over the past few years. In 1998, there were only 496 bariatric surgery procedures performed statewide. Between 1998 and 2005, bariatric surgery cases increased from 496 to 4,451, about an 800 percent (797.3%) increase. The year-to-year change was the highest between 2000 and 2001 (80.7%) and has been declining since. Between 2004 and 2005, the number of bariatric surgery cases has declined by 3.3% after showing a modest increase a year earlier. The annual number of bariatric surgeries appears to have leveled off to around 4,500. The reasons for the leveling off or the modest decline between 2004 and 2005 are unknown, but may reflect decisions by hospitals and/or surgeons to leave the field due to costs and/or increasing limitations or coverage exclusions by insurers/payers (Table 2).

TABLE 2. BARIATRIC SURGERY TRENDS IN NEW JERSEY, 1998 - 2005

(Diagnosis = 278.00, 278.01)

Year*	Procedure = 44.31, 44.38, 44.39, 44.68, 44.69, 44.95, 44.96, 44.97	Procedure = 43.7, 43.81, 43.89, 45.91	Combined Total	% Change
1998	356	140	496	-
1999	424	201	625	26.01
2000	799	298	1,097	75.52
2001	1,505	477	1,982	80.67
2002	2,435	781	3,216	62.26
2003	3,539	889	4,428	37.69
2004	4,222	383	4,605	4.00
2005**	4,374	77	4,451	-3.34

Source: New Jersey Uniform Billing Database 1998-2005.

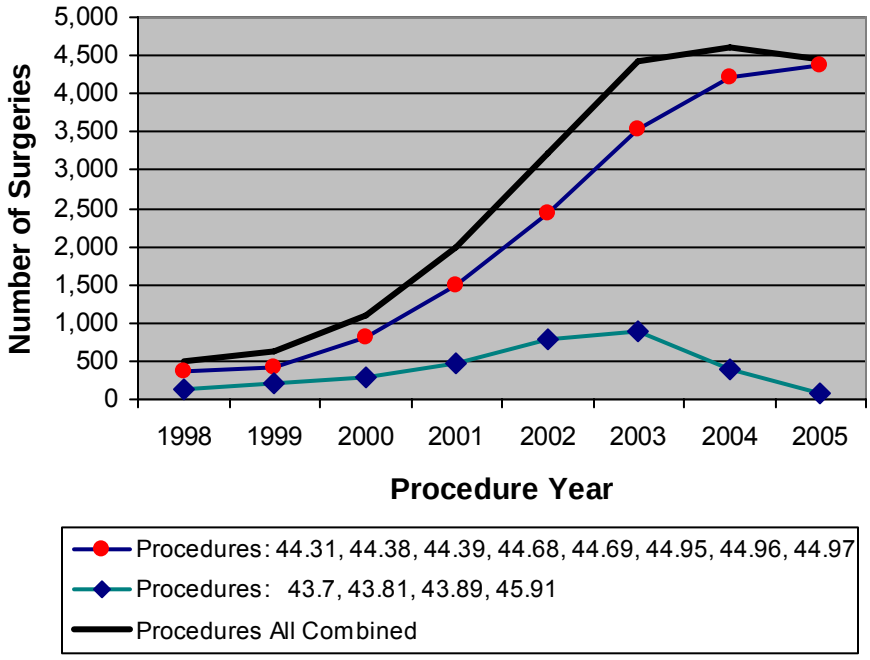
Notes:

* The numbers in this table are slightly different from those reported in the first report. That is because we used updated ICD-9-CM procedure codes and that also because the current report is based on admissions instead of discharges.

** Procedure codes 44.38, 44.68, 44.95, 44.96, and 44.97 are used in 2005 only.

Figure 2 shows trends in bariatric surgeries in New Jersey over the last seven years. The data lines in the graph clearly show that coding has become better defined, with almost no bariatric surgery cases being reported under ICD-9-CM codes of 43.7, 43.81, 43.89, and 45.91. These procedure codes are not used as often as in the past to report bariatric surgery cases.

Figure 2. Recent Trends in Bariatric Surgeries



Characteristics of Bariatric Surgery Patients

As indicated earlier, there were 4,451 bariatric surgeries performed in 2005. Over 70 percent (71.5%) of bariatric surgery patients were 30-54 years old, about 13 percent were under 30 years old and about 15 percent were 55 years old or older. Seventy nine percent of bariatric surgery patients were female (Table 3). Almost 87 percent (86.5%) of the bariatric surgeries were paid through private insurance providers, with Medicare accounting for only 6.1 percent, and Medicaid accounting for only 0.6 percent. It should be noted, however, that UB data do not distinguish between HMOs serving commercial and Medicaid members. Most New Jersey Medicaid clients under age 65 are enrolled in an HMO. Thus, the UB data show only Medicaid fee-for-service patients and likely understate Medicaid's share of bariatric surgery patients[2].

Severity of Illness and Risk of Mortality by Patient Characteristics

Tables 4 and 5 present characteristics of bariatric surgery patients by severity of illness and risk of mortality, respectively. Severity of illness and risk of mortality are obtained by using 3-M's proprietary grouper known as the All Patient Refined Diagnosis Related Groups (APR-DRG) which is a clinical model that expands on Diagnosis Related Groups (DRGs) on the basis of patient demographics and secondary diagnoses to identify patients with low, moderate, high and very high severity of illness or risk of mortality[3]. These classifications are disease-specific assigned by the APR-DRG to address differences in severity and risk of mortality for all patients across the several clinical conditions seen in an acute health care setting.

Table 4 shows that more than 96% of statewide bariatric surgery patients had low or moderate severity of illness. Eight of the nine in-hospital deaths (88.9%) occurred among patients identified as having high or very high severity of illness.

Table 5 shows that 99% of statewide bariatric surgery patients had low or moderate risk of mortality. Six of nine in-hospital deaths (67%) occurred among patients with high or very high risk of mortality.

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[2] The Division of Medical Assistance and Health Services, which administers New Jersey's Medicaid program, reported that there were 114 gastric bypass surgeries in 2003 covered by Medicaid HMOs. Including this information, the private insurance share would drop to 85% and the Medicaid share would rise to 3%.

[3] ***Severity of illness*: low** = minor loss of function (includes cases with no comorbidity or complication), **moderate** = moderate loss of function, **high** = major loss of function, **very high** = extreme loss of function.
***Risk of mortality*: low** = minor likelihood of dying, **moderate** = moderate likelihood of dying, **high** = Major likelihood of dying, **very high** = extreme likelihood of dying.

There is no variation in severity of illness or risk of mortality by gender. On the other hand, some variation is observed by payer type. For example, more than 19 percent (19.2%) of Medicaid patients had high or very high severity of illness while only 7.7% were high or very high for risk of mortality.

TABLE 3. DEMOGRAPHIC CHARACTERISTICS OF BARIATRIC SURGERY PATIENTS - 2005

Age Group	**Total**	**Column %**
15-19	56	1.3
20-24	172	3.9
25-29	359	8.1
30-34	548	12.3
35-39	677	15.2
40-44	705	15.8
45-49	685	15.4
50-54	569	12.8
55-59	412	9.3
60-64	191	4.3
65-69	63	1.4
70+	14	0.3
Total	**4,451**	**100.0**
Sex		
Female	3,518	79.0
Male	933	21.0
Total	**4,451**	**100.0**
Payer		
Medicare	272	6.1
Medicaid	26	0.6
Private	3,852	86.5
Self Pay	98	2.2
Other	203	4.6
Total	**4,451**	**100.0**

Source: New Jersey 2005 and 2006 UB Data.

TABLE 4. DEMOGRAPHIC CHARACTERISTICS OF BARIATRIC SURGERY PATIENTS BY SEVERITY OF ILLNESS - 2005

	SEVERITY OF ILLNESS (APR-DRG)*				
Age Group	**Low**	**Moderate**	**High**	**Very High**	**Total**
15-19	62.5	35.7	1.8	0.0	56
20-24	66.3	30.8	2.3	0.6	172
25-29	61.3	37.0	1.7	0.0	359
30-34	62.8	34.7	2.0	0.5	548
35-39	58.2	39.0	2.2	0.6	677
40-44	52.1	43.7	3.0	1.3	705
45-49	50.4	46.9	2.2	0.6	685
50-54	53.1	42.0	3.7	1.2	569
55-59	43.2	50.2	5.3	1.2	412
60-64	44.5	46.1	8.9	0.5	191
65-69	39.7	54.0	4.8	1.6	63
70+	35.7	42.9	14.3	7.1	14
Total	**54.2**	**41.9**	**3.1**	**0.8**	**4,451**
Sex					
Female	57.5	39.1	2.7	0.7	3518
Male	41.8	52.3	4.7	1.2	933
Total	**54.2**	**41.9**	**3.1**	**0.8**	**4,451**
Payer					
Medicare	29.8	61.0	7.4	1.8	272
Medicaid	34.6	46.2	11.5	7.7	26
Private	55.7	40.9	2.7	0.7	3,852
Self Pay	70.4	27.6	1.0	1.0	98
Other	54.2	40.4	4.9	0.5	203
Total	**54.2**	**41.9**	**3.1**	**0.8**	**4,451**
Deaths	**1**	**0**	**3**	**5**	**9**

Source: New Jersey 2005 and 2006 UB Data.

* Percent of row total

TABLE 5. DEMOGRAPHIC CHARACTERISTICS OF BARIATRIC SURGERY PATIENTS BY RISK OF MORTALITY - 2005

	RISK OF MORTALITY (APR-DRG)*					
Age Group	**Low**	**Moderate**	**High**	**Very High**	**Total**	**Deaths****
15-19	98.2	1.8	0.0	0.0	56	.
20-24	95.3	4.7	0.0	0.0	172	.
25-29	97.8	2.2	0.0	0.0	359	.
30-34	96.7	2.6	0.4	0.4	548	1
35-39	96.5	2.8	0.3	0.4	677	1
40-44	94.8	4.0	0.9	0.4	705	2
45-49	95.9	3.2	0.7	0.1	685	1
50-54	92.4	6.0	0.9	0.7	569	.
55-59	92.0	6.3	0.7	1.0	412	2
60-64	89.0	10.5	0.5	0.0	191	2
65-69	88.9	7.9	3.2	0.0	63	.
70+	42.9	28.6	21.4	7.1	14	.
Total	**94.7**	**4.2**	**0.7**	**0.4**	**4,451**	**9**
Sex						
Female	95.1	3.9	0.6	0.3	3518	5
Male	93.1	5.5	0.8	0.6	933	4
Total	**94.7**	**4.2**	**0.7**	**0.4**	**4451**	**9**
Payer						
Medicare	85.7	10.7	3.3	0.4	272	1
Medicaid ***	80.8	11.5	0.0	7.7	26	.
Private	95.4	3.7	0.5	0.4	3852	8
Self Pay	94.9	4.1	1.0	0.0	98	.
Other	95.1	4.9	0.0	0.0	203	.
Total	**94.7**	**4.2**	**0.7**	**0.4**	**4451**	**9**
Deaths	**1**	**2**	**1**	**5**	**9**	

Source: New Jersey 2005 and 2006 UB Data.

* Percent of row total

** Deaths are those during the initial admission.

Severity of Illness and Risk of Mortality by Hospital

Based on the 2005 UB data, only 32 hospitals in New Jersey performed bariatric surgeries[4] after counting those hospitals that have reported at least five bariatric surgeries in the year. The Department analyzed both severity of illness and risk of mortality by hospital to assess variations in the severity of illness and risk of mortality measures.

Table 6 presents the distribution of bariatric surgery patients by severity of illness within each hospital. We observe that severity of illness varies by hospital with 28.6 percent of bariatric surgery patients at Muhlenberg Regional Medical Center and 20.6 percent at Barnert Hospital assessed with high or very high severity of illness. By comparison, three hospitals --St. Claire's Hospital-Dover, Union Hospital and Somerset Medical Center had no bariatric surgery patients that scored high or very high. Over sixteen percent (16.1%) of bariatric surgery patients at Holy Name Hospital, and 10.5 percent in Trinitas Hospital had high or very high severity of illness scores.

By volume, two hospitals (Hackensack University Medical Center and Morristown Memorial Hospital) accounted for 34.7% of all bariatric surgeries, with four of the 32 hospitals (Hackensack University Medical Center (20.8%), Morristown Memorial Hospital (13.9%), St. Barnabas Medical Center (9.4%), and AtlantiCare Regional Medical Center-City (6.2%)) performing more than 50 percent (50.3%) of statewide bariatric surgeries in 2005.

Table 7 shows the distribution of bariatric surgery patients by risk of mortality within each hospital. The bariatric surgery patient population shows a substantial variation by risk of mortality. Several hospitals had 0.0 percent of their patients that scored high or very high for risk of mortality. On the other hand, Barnert Hospital, St. Clare's Hospital – Denville, St. Joseph's Hospital and Medical Center, and Union Hospital had five or more percent of their bariatric surgery patients who scored high or very high for risk of mortality. Twenty percent of bariatric surgery patients at Union Hospital were scored as high risk cases.

[4] Hospitals with less than 5 cases were removed to minimize anomalies resulting from coding errors. The Department for its 2003 report had contacted all hospitals that reported fewer than five cases to determine if they were truly performing bariatric surgeries to find out that such low volume hospitals did not.

TABLE 6. SEVERITY OF ILLNESS OF BARIATRIC SURGERY PATIENTS BY HOSPITAL - 2005

HOSPITAL	SEVERITY OF ILLNESS (APR-DRG)*				Total	Column %
	Low	Moderate	High	Very High		
AtlantiCare Regional Medical Center-City	56.5	41.7	1.1	0.7	276	6.2
Barnert Hospital	11.8	67.6	14.7	5.9	34	0.8
CentraState Medical Center	55.9	39.8	3.2	1.1	93	2.1
Chilton Memorial Hospital	42.3	50.0	5.8	1.9	104	2.3
Englewood Hospital and Medical Center	62.3	32.1	3.8	1.9	106	2.4
Hackensack University Medical Center	61.6	36.4	1.6	0.3	925	20.8
Holy Name Hospital	35.5	48.4	12.9	3.2	62	1.4
Jersey City Medical Center	47.4	47.4	5.3	0.0	19	0.4
Lourdes Medical Center of Burlington Cty.	45.6	49.6	4.0	0.8	125	2.8
Monmouth Medical Center	40.6	55.1	4.3	0.0	69	1.6
Morristown Memmorial Hospital	58.4	39.0	2.3	0.3	620	13.9
Mountainside Hospital	38.9	60.0	0.0	1.1	95	2.1
Muhlenberg Regional Medical Center	21.4	50.0	28.6	0.0	14	0.3
Newark Beth Israel Medical Center	43.6	48.7	7.7	0.0	78	1.8
Our Lady of Lourdes Medical Center	22.9	70.5	4.2	2.4	166	3.7
Overlook Hospital	61.1	35.7	3.2	0.0	126	2.8
Pascack Valley Hospital	66.7	29.6	3.7	0.0	27	0.6
Raritan Bay Medical Center-Perth Amboy	43.9	54.9	1.2	0.0	82	1.8
RWJ University Hospital	47.8	49.5	2.2	0.5	184	4.1
Somerset Medical Center	65.7	34.3	0.0	0.0	102	2.3
South Jersey Healthcare Regional MC	46.2	44.6	7.6	1.6	249	5.6
St. Barnabas Medical Center	69.7	27.7	2.4	0.2	419	9.4
St. Clare's Hospital-Denville	41.9	45.2	9.7	3.2	31	0.7
St. Clare's Hospital-Dover	71.1	28.9	0.0	0.0	38	0.9
St. Francis Medical Center-Trenton	42.3	51.9	5.8	0.0	52	1.2
St. Joseph's Hospital and Medical Center	33.3	54.2	8.3	4.2	24	0.5
Trinitas Hospital	52.6	36.8	10.5	0.0	19	0.4
UMDNJ-University Hospital	42.9	53.6	0.0	3.6	28	0.6
Union Hospital	40.0	60.0	0.0	0.0	5	0.1
University Medical Center at Princeton	51.9	44.2	1.9	1.9	156	3.5
Valley Hospital	66.2	32.4	0.0	1.4	74	1.7
Virtua-Memorial Hospital Burlington Cty.	30.6	63.3	4.1	2.0	49	1.1
Total	**54.2**	**41.9**	**3.1**	**0.8**	**4,451**	**100.0**

Source: New Jersey 2005 and 2006 UB Data.

* Percent of row total

TABLE 7. RISK OF MORTALITY OF BARIATRIC SURGERY PATIENTS BY HOSPITAL - 2005

HOSPITAL	RISK OF MORTALITY (APR-DRG)*				Total
	Low	Moderate	High	Very High	
AtlantiCare Regional Medical Center-City	96.4	2.9	0.4	0.4	276
Barnert Hospital	79.4	14.7	0.0	5.9	34
CentraState Medical Center	95.7	2.2	1.1	1.1	93
Chilton Memorial Hospital	87.5	10.6	1.9	0.0	104
Englewood Hospital and Medical Center	90.6	6.6	1.9	0.9	106
Hackensack University Medical Center	96.6	2.9	0.3	0.1	925
Holy Name Hospital	87.1	9.7	1.6	1.6	62
Jersey City Medical Center	94.7	5.3	0.0	0.0	19
Lourdes Medical Center of Burlington Cty.	94.4	4.8	0.0	0.8	125
Monmouth Medical Center	95.7	4.3	0.0	0.0	69
Morristown Memmorial Hospital	97.3	2.4	0.2	0.2	620
Mountainside Hospital	95.8	3.2	1.1	0.0	95
Muhlenberg Regional Medical Center	78.6	21.4	0.0	0.0	14
Newark Beth Israel Medical Center	89.7	7.7	2.6	0.0	78
Our Lady of Lourdes Medical Center	91.0	6.6	1.8	0.6	166
Overlook Hospital	96.8	3.2	0.0	0.0	126
Pascack Valley Hospital	96.3	3.7	0.0	0.0	27
Raritan Bay Medical Center-Perth Amboy	97.6	2.4	0.0	0.0	82
RWJ University Hospital	95.1	4.3	0.5	0.0	184
Somerset Medical Center	99.0	1.0	0.0	0.0	102
South Jersey Healthcare Regional MC	89.2	8.4	2.0	0.4	249
St. Barnabas Medical Center	95.9	3.8	0.0	0.2	419
St. Clare's Hospital-Denville	87.1	6.5	3.2	3.2	31
St. Clare's Hospital-Dover	94.7	5.3	0.0	0.0	38
St. Francis Medical Center-Trenton	94.2	5.8	0.0	0.0	52
St. Joseph's Hospital and Medical Center	75.0	16.7	4.2	4.2	24
Trinitas Hospital	89.5	10.5	0.0	0.0	19
UMDNJ-University Hospital	92.9	3.6	0.0	3.6	28
Union Hospital	60.0	20.0	20.0	0.0	5
University Medical Center at Princeton	95.5	2.6	0.6	1.3	156
Valley Hospital	97.3	1.4	1.4	0.0	74
Virtua-Memorial Hospital Burlington Cty.	91.8	4.1	2.0	2.0	49
Total	**94.7**	**4.2**	**0.7**	**0.4**	**4,451**

Source: New Jersey 2005 and 2006 UB Data.

* Percent of row total

Bariatric Surgery by Hospital Volume and Readmissions

Table 8 presents bariatric surgery by hospital volume, 30-day readmissions, 180-day readmissions, in-hospital mortality and 30-day mortality. Hospital level readmission rates and mortality rates are presented in Table 9.

Table 8 shows that 13 hospitals performed 100 or more surgeries in 2005, accounting for 3,558 (79.9%). The remaining 19 hospitals accounted for only 893 (20.1%) surgeries. There is a clear negative relationship between bariatric surgery volume and readmissions rate, with low volume hospitals showing higher readmission rates. This relationship is evident both in short-term readmissions (30-day readmission rates) and longer-term readmissions (180-day readmission rates). Readmission rates are assessed by taking patients readmitted for directly related complications (see discussion later). As expected, 180-day readmission rates are higher than 30-day readmission rates, suggesting that complications following bariatric procedures can still manifest long after the procedure is performed.

Table 8 also presents in-hospital and 30-day crude mortality rates by hospital volume to assess the degree to which hospital volume is related to bariatric surgery mortality. The data show that five of the nine (55.6%) initial or in-hospital deaths occurred in hospitals that performed fewer than 100 bariatric surgeries. Similarly, seven of the thirteen 30-day bariatric deaths (53.8%) occurred in these low volume hospitals. Given that these hospitals performed only 20.1 percent (893) of the total surgeries in 2005, this suggests that there is an inverse relationship between hospital bariatric surgery volume and mortality.

TABLE 8. HOSPITAL VOLUME, MORTALITY AND READMISSIONS - 2005

HOSPITAL VOLUME	NUMBER OF HOSPITALS	INITIAL BARIATRIC PROCEDURES	READMISSION WITHIN 30 DAYS			READMISSION WITHIN 180 DAYS			IN-HOSPITAL MORTALITY		30-DAY MORTALITY	
			N	TOTAL	RATE (%)	N	TOTAL	RATE (%)	N	RATE (%)	N	RATE (%)
<10	1	5	2	2	40.00	2	2	40.00	0	0.00	0	0.00
10 - 24	4	76	7	9	9.21	11	16	14.47	1	1.32	1	1.32
25 - 49	6	207	21	22	10.14	35	54	16.91	1	0.48	2	0.97
50 - 99	8	605	45	50	7.44	70	113	11.57	3	0.50	4	0.66
100 - 249	9	1,318	106	117	8.04	155	206	11.76	0	0.00	1	0.08
250 - 499	2	695	42	48	6.04	56	67	8.06	0	0.00	0	0.00
500+	2	1,545	93	102	6.02	129	151	8.35	4	0.26	5	0.32
TOTAL	**32**	**4,451**	**316**	**350**	**7.10**	**458**	**609**	**10.29**	**9**	**0.20**	**13**	**0.29**

Source: New Jersey 2005 and 2006 UB Data.

N = Number of readmitted patients

TOTAL = Total number of readmissions among readmitted patients

Note: Readmission rate is culculated as 100*(N/Initial Bariatric Procedures).

Readmission by Hospital

Table 9 presents 30-day and 180-day readmission rates by hospital as well as in-hospital and 30-day mortality for each hospital. Statewide, 7.1 percent of bariatric surgeries were readmitted within 30 days of initial discharge compared to 13.7 percent for 180-day readmissions[5]. By hospital, 30-day readmission rates varied from 0.0% at Trinitas Hospital to 40.0% at Union Hospital. Consistent with previous findings, readmission rates appear to be lower among high volume hospitals compared with low volume hospitals. For example, high volume hospitals such as Hackensack, Morristown, St. Barnabas, AtlantiCare, and South Jersey Healthcare Regional MC had lower readmission rates compared to low volume hospitals (Union and Muhlenberg).

Bariatric Surgery Mortality

The mortality rate from bariatric surgery is very low. There were nine in-hospital deaths among bariatric surgery cases in 2005, resulting in an in-hospital crude mortality rate of 0.20%. Our analysis also looked at mortality 30 days after surgery. In order to do this, in cases where deaths occurred after the initial discharge, the Department staff looked for any other UB records for the same patient to identify deaths occurring up to 30 days after the initial admission. For analytical purposes, the subsequent record was linked to the initial surgery, not only to determine mortality rates, but also 30-day readmission and 180-day complication rates and total hospital stay days. This analysis, which used both the 2005 and 2006 UB data sets to account for 30-day mortality uncovered four additional deaths for a total of 13, resulting in a statewide mortality rate of 0.29%. Similar to readmission rates, the analysis suggests an inverse relationship between hospital volume and bariatric surgery mortality.

[5] A study conducted using 1995-2004 California hospital discharge data found that 20.2% of patients were readmitted one year after Roux-en-Y gastric bypass (RYGB) surgery (Zingmond et al. “Hospitalization Before and After Gastric Bypass Surgery,” JAMA, October 19, 2005, Vol. 294, No. 15: 1918-1924).

Bariatric Surgery Complications and Mortality by Surgeon Volume

The Department used primary and secondary diagnosis codes recommended by the Work Group to identify directly related complications on readmitted patients (see Appendix A). These directly related complication codes were searched for each readmitted patient within 180 days after surgery. Complications for a readmitted patient may be reported either as a primary diagnosis or under one or more of the eight secondary diagnoses of subsequent readmissions in the UB data. Thus, any readmitted patient potentially has up to nine complications per readmission. In principle, therefore, a complication rate could exceed 100% of readmissions because of multiple diagnoses/complications. The summary of complication rates by surgeon volume is presented in Table 9 while Table 10 displays complication rates by hospital.

Table 10 shows that 108 surgeons performed the 4,451 bariatric surgeries in 2005, with 16 of these surgeons performing 62 percent (2,759) of the surgeries. Fifty-five out of the 108 surgeons (50.9%) performed between 1-9 cases only (see Table 10).

It was also of interest to assess how surgeon volume relates to mortality among bariatric surgery patients. Staff, therefore, analyzed both in-hospital and 30-day mortality rates by surgeon volume. Table 10 presents the crude mortality rates by surgeon volume but doesn't suggest a clear pattern of association between volume and bariatric surgery mortality. This erratic pattern may in part be due to the small number of bariatric surgery deaths. However, when we regroup surgeon volumes into four approximately equal sized categories (1-49, 50-99, 100-159, and 160+), we find a clearer inverse relationship between surgeon volume and both in-hospital and 30-day mortality rates. The 30-day mortality rates for these categories were 0.93 percent, 0.0 percent, 0.29 percent and 0.17 percent, respectively. This is consistent with previous findings on the relationship we observed between hospital volume and mortality as well as hospital volume and readmissions.

Complications

Examining the extent of complications following bariatric surgery was one of the most vital components of this analysis. To assess complications, an extensive search of directly-related complications (see Appendix A) that occurred over 180 days after surgery was made among all readmitted patients. A patient could have multiple complications within each admission provided that the ICD-9-CM code falls within the list of complications identified earlier.

There were 553 directly related complications within 180 days of the bariatric procedure among the 4,451 patients. This represents a 12.4 percent complication rate. Complication rates were highest (27.8%) among the low surgeon volume (1-9 volume) group followed by the 20-49 surgeon volume group (24.0%). The lowest complication rate (9.8%) was among surgeons performing 160 or more cases a year. Complications rates tend to decline as surgeon volume increases suggesting, once again, the importance of surgeon volume for positive bariatric surgery outcome.

Table 11 presents the number of readmissions and directly-related complications 180 days post surgery for each of the 32 hospitals performing bariatric surgery. The table also presents the average number of complications per bariatric surgery patient and the corresponding complication rate. The statewide rate for directly-related complications was estimated at 12.4 percent.

Over 10 percent (10.3%) of the 4,451 bariatric surgery patients were readmitted within 180 days after the surgery for directly related complications. There were a total of 609 readmissions of which 319 were for directly-related complications following their bariatric surgeries. The total number of complications reported by these 319 readmissions was 553 resulting in an average of 1.7 per patient that is attributable to directly-related complications.

Table 11 also suggests an inverse relationship between volume and complication rate where there is a tendency for higher volume hospitals to exhibit lower complication rates. This tendency is clearly evidenced by data showing that the high volume hospitals such as Hackensack (7.1%), Morristown (17.4%), St. Barnabas (6.2%), AtlantiCare (7.3%), and South Jersey Regional MC (14.9%) have significantly lower complication rates compared to the low volume hospitals such as Union (40.0%), Muhlenberg (57.1%), Pascack Valley (59.3%), and Jersey City (36.8%).

TABLE 11. COMPLICATIONS DIRECTLY-RELATED TO BARIATRIC SURGERY BY HOSPITAL - 2005

(READMISSIONS WITHIN 180 DAYS)

HOSPITAL	Total number of bariatric surgeries	Total number of readmitted patients	Total number of readmissions	Total number of readmissions due to directly-related complications	Total # of complications among patients readmitted for directly-related complications	Average number of complications per patient*	Rate of complications (%)**
AtlantiCare Regional Medical Center-City	276	17	19	12	20	1.7	7.25
Barnert Hospital	34	6	8	4	9	2.3	26.47
CentraState Medical Center	93	9	19	10	21	2.1	22.58
Chilton Memorial Hospital	104	14	17	9	15	1.7	14.42
Englewood Hospital and Medical Center	106	14	18	10	18	1.8	16.98
Hackensack University Medical Center	925	67	78	35	66	1.9	7.14
Holy Name Hospital	62	11	18	11	20	1.8	32.26
Jersey City Medical Center	19	3	4	4	7	1.8	36.84
Lourdes Medical Center of Burlington Cty.	125	17	21	14	21	1.5	16.80
Monmouth Medical Center	69	1	2	0	0	.	0.00
Morristown Memmorial Hospital	620	62	73	54	108	2.0	17.42
Mountainside Hospital	95	8	11	6	9	1.5	9.47
Muhlenberg Regional Medical Center	14	4	6	5	8	1.6	57.14
Newark Beth Israel Medical Center	78	11	13	3	5	1.7	6.41
Our Lady of Lourdes Medical Center	166	21	32	18	24	1.3	14.46
Overlook Hospital	126	11	14	9	15	1.7	11.90
Pascack Valley Hospital	27	6	9	7	16	2.3	59.26
Raritan Bay Medical Center-Perth Amboy	82	15	29	22	34	1.5	41.46
RWJ University Hospital	184	18	21	11	17	1.5	9.24
Somerset Medical Center	102	10	16	7	7	1.0	6.86
South Jersey Regional MC	249	25	35	20	37	1.9	14.86
St. Barnabas Medical Center	419	39	48	18	26	1.4	6.21
St. Clare's Hospital-Denville	31	7	9	4	10	2.5	32.26
St. Clare's Hospital-Dover	38	1	4	0	0	.	0.00
St. Francis Medical Center-Trenton	52	7	11	6	8	1.3	15.38
St. Joseph's Hospital and Medical Center	24	4	6	0	0	.	0.00
Trinitas Hospital	19	0	0	0	0	.	0.00
UMDNJ-University Hospital	28	6	11	0	0	.	0.00
Union Hospital	5	2	2	1	2	2.0	40.00
University Medical Center at Princeton	156	25	32	10	16	1.6	10.26
Valley Hospital	74	8	10	4	6	1.5	8.11
Virtua-Memorial Hospital Burlington Cty.	49	9	13	5	8	1.6	16.33
Total	**4,451**	**458**	**609**	**319**	**553**	**1.7**	**12.42**

Source: New Jersey 2005 and 2006 UB Data.

* Average number of complications refers to the number of complications per patient among those readmitted because of directly-related complication.

** Complications rate refers to the number of directly-related complications per 100 bariatric procedures.

Bariatric Surgery and Hospital Length of Stay

Both providers and insurers believe that it's the relatively small number of bariatric surgery cases involving extremely serious complications that drive up the costs of the procedure. These are the cases where complications do not cause immediate death but require long hospitalizations. These are also the cases that may generate extensive publicity. In an effort to provide an indication of the volume of such long-stay cases involving complications, this study added together all hospital days for the initial admission for bariatric surgery as well as any readmission associated with a directly-related complication within 180 days of surgery. Length of hospital stay by 2005 bariatric surgery patients was captured both from the 2005 and 2006 UB data sets. Table 12 presents the statewide distribution of bariatric surgery patients by length of hospital stay days.

The majority of patients (58%) stayed for two days or less, while 30.6 percent stayed an average of 3–4 days. There were 334 patients (7.6 percent) who stayed for 5-9 days and 79 patients (1.8 percent) who spent an average of 10–14 days in a hospital. Ninety-one patients (1.9%), spent between 15 and 180 days in hospital either during their bariatric surgery admission or a subsequent admission; thirty-two of these patients (0.7%), had hospital stays that exceeded 30 days. The data suggest that there is a small subset of bariatric surgery patients who experience severe and costly complications.

Table 13 presents average length of hospital stays by hospital. The average length of hospital stay ranged from a low of 1.3 days at Valley Hospital to a high of 8.8 days at Union Hospital. Generally, the high volume hospitals tend to have shorter lengths of hospital stay. The average length of hospital stay for all the 4,451 bariatric patients in 2005 was 3.2 days.

TABLE 12. STATEWIDE BARIATRIC SURGERY PATIENTS BY LENGTH OF HOSPITAL STAY IN DAYS - 2005

LENGTH OF HOSPITAL STAY IN DAYS*	NUMBER OF PATIENTS	PERCENT
<=2	2,595	58.0
3-4	1,352	30.6
5-9	334	7.6
10-14	79	1.8
15-19	31	0.6
20-24	20	0.4
25-29	8	0.2
30-49	14	0.3
50-79	12	0.3
80-180	6	0.1
Total	**4,451**	**100.0**

Source: New Jersey 2005 and 2006 UB Data.

* Total days for the initial admission as well as for each readmission to any New Jersey hospital for a directly related complication.

TABLE 13. LENGTH OF HOSPITAL STAYS (IN DAYS) BY HOSPITAL - 2005

HOSPITAL	TOTAL NUMBER OF BARIATRIC SURGERIES	TOTAL NUMBER OF HOSPITAL STAY DAYS*	AVERAGE NUMBER OF HOSPITAL STAY DAYS
AtlantiCare Regional Medical Center-City	276	533	1.9
Barnert Hospital	34	192	5.6
CentraState Medical Center	93	337	3.6
Chilton Memorial Hospital	104	260	2.5
Englewood Hospital and Medical Center	106	505	4.8
Hackensack University Medical Center	925	2,576	2.8
Holy Name Hospital	62	455	7.3
Jersey City Medical Center	19	73	3.8
Lourdes Medical Center of Burlington Cty.	125	495	4.0
Monmouth Medical Center	69	159	2.3
Morristown Memmorial Hospital	620	1,371	2.2
Mountainside Hospital	95	211	2.2
Muhlenberg Regional Medical Center	14	97	6.9
Newark Beth Israel Medical Center	78	399	5.1
Our Lady of Lourdes Medical Center	166	808	4.9
Overlook Hospital	126	347	2.8
Pascack Valley Hospital	27	114	4.2
Raritan Bay Medical Center-Perth Amboy	82	259	3.2
RWJ University Hospital	184	498	2.7
Somerset Medical Center	102	271	2.7
South Jersey Regional MC	249	1,371	5.5
St. Barnabas Medical Center	419	1,095	2.6
St. Clare's Hospital-Denville	31	267	8.6
St. Clare's Hospital-Dover	38	103	2.7
St. Francis Medical Center-Trenton	52	157	3.0
St. Joseph's Hospital and Medical Center	24	110	4.6
Trinitas Hospital	19	57	3.0
UMDNJ-University Hospital	28	132	4.7
Union Hospital	5	44	8.8
University Medical Center at Princeton	156	621	4.0
Valley Hospital	74	93	1.3
Virtua-Memorial Hospital Burlington Cty.	49	226	4.6
Total	**4,451**	**14,236**	**3.2**

Source: New Jersey 2005 and 2006 UB Data.

* includes all initial admissions as well as readmissions to any New Jersey hospital within 180 days.

Hospital Charges for Bariatric Surgery

Hospital charges statewide for bariatric surgeries in 2005 were $186 million. This figure does not include charges by surgeons or anesthesiologists. The Department has no data on physician charges. The average hospital charge per patient was about $42,000 with a substantial variation by hospital ranging from $19,804 at Valley Hospital to $77,941 at South Jersey Regional Medical center. However, it must be noted that hospital charges do not reflect the true cost of treatment, nor do they show actual payments hospitals receive for services provided. Public payers, such as Medicare and Medicaid (for patients not enrolled in an HMO) set the rates they will pay hospitals, regardless of charges. Private insurers typically negotiate deep discounts from the charge rate. In 2004, the statewide average ratio of hospital net patient service revenue to charges was 24.7%. Applying this ratio to the 2005 data suggests that the total amount of revenue actually collected by hospitals may have been closer to $45.9 million (24.7% x $186 million).

Insurance Coverage Issues

The first report indicated that the Work Group could not reach consensus on the issue of insurance coverage for obesity treatments, including bariatric surgery. Providers in the Work Group believe that the research is increasingly convincing that bariatric surgery is not only safe and effective, but also cost-effective in terms of its reduction of certain co-morbidities, such as diabetes and sleep apnea. Views of Work Group insurer representatives were not as specific as those of the providers.

CMS, in the past, specifically stated that obesity is not an illness. That statement has been withdrawn and CMS is now evaluating what types of obesity-related treatments it would cover under Medicare. In the meantime, bariatric surgery is covered under Medicare only to the extent that it is related to treating other illnesses.

While all the Work Group members agreed that objective criteria for medical necessity should be followed in determining coverage for bariatric surgery, and the NIH criteria were considered the most objective available, there still is no consensus about the application of these criteria in practice.

Private insurers, as mentioned earlier, have been stringent in determining whether patients meet clinical criteria for bariatric surgery. In New Jersey, insurers, reacting to the rapid growth of bariatric surgery are increasingly, where permitted, modifying their policies to offer riders to exclude coverage for such surgery and/or to impose high cost-sharing on patients (HMOs in New Jersey are not permitted to exclude bariatric surgery coverage). Insurers believe such riders offer reasonable methods to hold down the cost of health insurance for employers. They are also skeptical that the rapid growth in bariatric surgery has

all been driven by clinical necessity, and they are very concerned with the extraordinarily high costs of those few cases where severe complications result in very lengthy and costly hospitalizations.

Due to federal law, insurance coverage mandates enacted by the State have no effect on patients covered by Medicare or self-insured employers, representing roughly half of all New Jerseyans. Moreover, insurer and employer representatives argue that the increased costs associated with mandates result in reduction in the number of employers who offer health insurance as well as employees who sign up for it. Providers counter by pointing out the longer term savings resulting from reduced co-morbidities.

Survey Findings of Bariatric Surgery Hospitals

In the first Bariatric Surgery Report, the Work Group recommended that hospitals performing bariatric surgery adopt a comprehensive approach to the care of their bariatric surgery patients. In particular, data elements of care set forth by the American Society for Bariatric Surgery (ASBS) or the American College of Surgeons (ACS) were recommended for this comprehensive approach. The Department then conducted a short survey to assess the progress made by New Jersey hospitals in adopting this comprehensive approach. The survey, which covered only the 36 hospitals that performed bariatric surgery in 2003, was conducted in June 2006.

Thirty-two of the 36 hospitals completed the survey, for a response rate of 89 percent. Of these, only 23 hospitals (64%) indicated that they performed bariatric surgery through 2006. This was confirmed by checking the 2005 and 2006 UB data. Thirteen hospitals that reported performing bariatric surgery in 2003 did not perform the procedure in the period 2005-2006. Nine of the 32 hospitals included in the present report did not perform bariatric surgery in 2003. This indicates that the number of hospitals that perform bariatric surgery fluctuates from year-to-year and that the big majority of the surgeries are performed by a few high volume hospitals. For example, 80% of the surgeries in 2005 were performed by only 13 hospitals. By comparison, in 2003, 79% of the surgeries were performed by only 12 hospitals. The year-to-year fluctuations in the number of bariatric surgery hospitals may be the result of low volume hospitals not doing enough procedures to be included in the analysis.

The survey data show that five hospitals were designated '*Center of Excellence*' (an accreditation given to hospitals for adopting the recommended comprehensive approach to bariatric surgery) by either ACS or ASBS. Only one of these five hospitals, University Medical Center at Princeton, reported having accreditation from both ACS and ASBS. Fourteen hospitals indicated that they had either applied or had plans to apply for the accreditation.

Interestingly, only 20 hospitals indicated reading the first Bariatric Surgery Report while 11 hospitals replied that they did not read the report. Summary of findings of the survey are presented in Appendix B.

Conclusions and Recommendations

There is considerable clinical research regarding obesity. New prescription drugs to treat obesity are under development and may prove more effective than current pharmacological approaches. Medical device companies have developed a pacemaker-type device, which is being used in Europe that can be laparoscopically attached to the stomach to produce satiety. These and other as yet unknown treatments may emerge and will need to be examined to determine if they compare favorably to bariatric surgery in terms of safety, effectiveness, and cost. In the meantime, the Department will continue to use its hospital discharge data for periodic monitoring of bariatric surgery in consultation with expert stakeholders until better systems such as a bariatric surgery registry are in place.

A bariatric surgery registry would consist of patient-level bariatric surgery data separately submitted to the Department by all hospitals that perform such surgeries. Typically, such a registry would include socio-demographic data and an extensive list of clinical data. Generally, the data would be abstracted from patients' medical records for the specific purpose of submission to the bariatric surgery data registry. The data elements abstracted would be those that experts would consider most relevant to assessing the quality of bariatric surgery. The Department has no plans to pursue a state registry until there is a clear consensus on a standardized set of data elements for the registry. In addition, the Department does not have the resources to develop a registry at this time.

The UB database suggests some important trends and hospital and surgeon characteristics that affect positive bariatric surgery outcomes. Variations by gender, age and health insurance status are also noted for proper understanding of the bariatric surgery population.

Bariatric surgery appears to have stabilized at around 4,500 cases per year suggesting a possible maturing of the practice in the state. The largest group utilizing this weight reduction surgery continues to be females (79%) with 30-54 year olds accounting for 71.5% of all bariatric surgeries in 2005.

Over 86% (86.5%) of bariatric surgery patients had private insurance and 6.1% had Medicare. Health coverage that includes not only bariatric surgery, but also pre- and post-operative counseling and nutritional supplements give patients the best chance of succeeding in their weight reduction goal. Such related services and products are rarely covered by insurance and may pose significant treatment barriers, particularly for lower income patients.

Large volume hospitals tended to have lower readmission rates as well as lower 30-day mortality rates. There is also an inverse relationship between surgeon volumes on the one hand and 30-day mortality rate and bariatric surgery complication rate 180 days post-surgery on the other. This strongly suggests that experience in performing bariatric surgery procedures is vital for positive outcomes.

On average, a bariatric surgery patient stayed in hospital for 3.2 days with hospital variations ranging from 1.3 days to 8.8 days.

In 2005, statewide hospital charges amounted to $186 million with only about $46 million (about $10,000 per patient) actually collected by hospitals for their services.

The Uniform Billing (UB) data have proven important for monitoring trends as well as outcomes of bariatric surgery. Until a bariatric surgery data registry is implemented that will allow for a more in-depth look at risk factors for bariatric surgery outcome, the Department will continue to monitor trends as well as significant outcomes by using the UB database.

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[21] Buchwald, et al., p. 1724.

APPENDIX A

DIAGNOSTIC CODES CONSIDERED TO BE DIRECTLY-RELATED BARIATRIC SURGERY COMPLICATIONS

Diagnosis Codes	Description
9974	Digestive system complications
99859	Other postoperative infection
2765	Volume depletion
41519	Pulmonary embolism - other
53190	Gastric ulcer
486	Pneumonia
53440	Gastrojejeunal ulcer with bleeding
5770	Acute pancreatitis
99669	Infection due to other device
99811	Hemorrhage
51881	Acute respiratory failure
53019	Other esophagitis
53081	Esophageal reflux
5370	Pyloric stenosis
55221	Incisional hernia with obstruction
5589	Gastroenteritis and colitis
5609	Unspecified intestinal obstruction
5642	Post gastric surgery syndrome
56981	Intestinal fistula
78701	Nausea with vomiting
99883	Non-healing surgical wound
2859	Acute post-hemmorphagge anemia
30401	Opiate dependence
41071	Anterior lateral MI
41511	Pulmonary embolism - infarction
42731	Atrial fibrillation
49322	Asthma with COPD
5272	Sialoadenitis
5303	Stricture of esophagus
53140	Gastric ulcer with bleeding
53470	Gastrojejeunal ulcer without bleeding or perforation
53490	Unspecified gastrojejeunal ulcer without bleeding or perforation
53500	Acute gastritis
53510	Atrophic gastritis
53641	Infection of gastrostomy
53649	Gastrostomy complications
53789	Other disorders of stomach
55220	Ventral hernia with obstruction
5531	Umbilical hernia
55320	Ventral hernia
55321	Incisional hernia
56039	Intestinal impaction
56081	Intestinal or peritoneal adhesions with obstruction
56089	Other intestinal obstruction
5643	Vomiting following GI surgery
56489	Disorders of intestine

APPENDIX A

DIAGNOSTIC CODES CONSIDERED TO BE DIRECTLY-RELATED BARIATRIC SURGERY COMPLICATIONS

Diagnosis Codes	Description
5672	Peritonitis
5693	Rectal bleeding
56982	Intestinal ulceration
57400	Gallbladder stones with acute cholecystitis
5781	Blood in stool
5793	Post-surgical nonabsorption
78703	Vomiting
7872	Dysphagia
78791	Diarrhea
78903	Abdominal swelling
78906	Abdominal tenderness
9961	Mechanical complications of device
99659	Mechanical complications of other devices
99662	Infection due to device
99674	Other complications of device
99679	Other complications of other devices
99832	Disrruption of operative wound
99851	Postoperative infection
9986	Postoperative fistula
V551	Attention of gastrostomy

Source: New Jersey 2005 and 2006 UB Data

APPENDIX B

BASELINE SURVEY ON HOSPITALS PERFORMING BARIATRIC SURGERY IN NEW JERSEY - SUMMARY

Questions	Percent (N=36)			
	Yes	No	NA	NR
Is hospital currently performing surgery?	61.1	27.8	0.0	11.1
Is hospital designated as center of excellence by ACS?	2.8	61.1	25.0	11.1
Is hospital designated as center of excellence by ASBS?	13.9	50.0	25.0	11.1
If designated, date of certification	-	-	-	-
If not designated yet, have you submitted application?	22.2	27.8	36.1	13.9
If no, do you plan to submit application in CY2006	16.7	5.6	61.1	16.7
Is there medical director specifically for the bariatric surgery program?	27.8	13.9	30.6	27.8
Are the hospital's bariatric surgeon(s) board certified surgeons and do they spend a significant portion of their practice doing bariatric surgery?	33.3	11.1	27.8	27.8
Does the hospital has nurse and/or physician extenders dedicated to serving bariatric surgery patients?	25.0	19.4	27.8	27.8
Does the hospital maintain a full line of appropriately sized furniture, equipment and instruments used in caring for bariatric surgical patients?	44.4	0.0	27.8	27.8
Does the hospital provide an ongoing, regularly scheduled in-service education program in bariatric surgery?	30.6	13.9	27.8	27.8
Does the hospital maintain, within 30 minutes of request, a full complement of staff required to care for bariatric surgical patients, including immediate availability of an ACLS-qualified physician?	44.4	0.0	27.8	27.8
Does the hospital use clinical pathways and orders that facilitate the standardization of pre-operative bariatric surgery care?	27.8	13.9	30.6	27.8
Did the hospital perform at least 125 bariatric surgery cases in 2005, including primary operations, emergencey procedures and/or revisions?	13.9	30.6	27.8	27.8
Did all bariatric surgeons credentialed by the hospital, perform at least 50 bariatric surgery cases in 2005, including cases performed at other hospitals?	27.8	16.7	27.8	27.8
Does the hospital make available, organized support groups for patients who have had bariatric surgery?	38.9	5.6	27.8	27.8
Does the hospital maintain a system for tracking surgical outcomes and follows at leat 75% of its bariatric surgery patients for five years after surgery?	25.0	19.4	27.8	27.8
Prior to receiving this survey, had you read the Bariatric Surgery Work Group's report?	55.6	30.6	0.0	13.9

NA - Not Applicable (does not apply following earlier response)

NR - No Response/missing although question applies, including the four that did not send in the form.

Appendix C

Overweight Prevention and Treatment Effectiveness: Evolving Consensus

- A useful framework for prevention and treatment modalities (Table C.1) has been developed by Kaiser Permanente, a large health management organization. Recommended prevention / treatment options, based on risk, are as follows:[1]

Table C.1

Prevention / Treatment Options Based on Risk

Health Risk	Prevention/Treatment Options
Minimal and Low	Healthful eating and/or moderate deficit diet Increased physical activity Lifestyle change strategies
Moderate	All of the above plus low calorie diet
High and Very High	All of the above plus pharmacotherapy and very low calorie diet
Extremely High	All of the above plus surgical intervention

Kaiser Permanente also offers a useful longitudinal approach to preventing obesity :[2]

Table C.2

Longitudinal Approach to Preventing Obesity

Infants	Toddlers	Children	Adults
Promote:	Promote:	Increase:	Increase:
Breastfeeding	Breastfeeding	Physical Activity	Physical Activity
	Healthy Eating Behaviors		
		Decrease:	Decrease:
		TV Viewing	Portion Size
		Sweetened Beverage Consumption	
		Unhealthy Eating Behaviors	Encourage:
			Weight Maintenance

[1] Kaiser Permanente, "Background Paper on the Prevention and Treatment of Overweight and Obesity," August 2003, p. 7.

[2] idib, p. 9.

- In 1998, the NIH completed an exhaustive review of the then available medical literature and published "Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report."[3] According to this report:

    1. **Low-calorie diets (LCDs)** can reduce total body weight by an average of eight percent over three to 12 months. No improvement in cardio-respiratory fitness appears to occur in overweight or obese adults who lose weight on LCDs without increasing physical activity. LCD diets resulting in weight loss cause a decrease in abdominal fat. Increased abdominal fat appears to be an independent risk predictor when the BMI is not markedly increased. According to the NIH, a high waist circumference-->35 inches for women and > 40 inches for men—is associated with an increased risk for type-2 diabetes, dyslipidemia, hypertension, and CVD in patients with a BMI between 25 and 34.9.

    2. **Very Low-Calorie Diets** produce greater initial weight loss than LCDs. However, the long-term (>1 year) weight loss is not different from that of the LCD.

    3. **Lower-Fat Diets (LFDs)** without targeted caloric reduction help promote weight loss when they have the effect of reducing caloric intake. LFDs that explicitly are coupled with total caloric reduction produce greater weight loss than LFDs alone.

    4. **Physical Activity** in overweight and obese adults results in modest weight loss independent of the effect of caloric reduction through diet. Physical activity in overweight and obese adults modestly reduces abdominal fat. Physical activity in overweight and obese adults increases cardio-respiratory fitness independent of weight loss.

    5. **Combined Reduced Calorie Diet & Increased Physical Activity** produce greater weight loss than diet alone or physical activity alone. This combination produces greater reductions in abdominal fat than either diet alone or physical activity alone. This combination produces improved cardio-respiratory fitness when compared to diet alone.

    6. **Behavior Therapy**, when used in combination with other weight loss approaches, provides additional benefits in assisting patients to lose weight short term (one year). No additional benefits are found at three to five years in the absence of continued intervention. No one behavior therapy appeared superior to any other in its effect on weight loss; rather, multimodal strategies appeared to work best and those interventions with the greatest intensity

[3] National Institutes of Health, "Clinical Guidelines on the Identification, evaluation, and Treatment of Overweight and Obesity in Adults: The evidence Report," Publication 98-4083, September 1998, pp. 42-55.

appeared to be associated with the greatest weight loss. Long-term follow-up of patients undergoing behavior therapy shows a return to baseline weight in the great majority of subjects in the absence of continued behavioral intervention. Little evidence exists on the effect of behavior therapy in combination with diet and physical activity on cardio-respiratory fitness.

7. **Pharmacotherapy**, which is generally studied along with lifestyle modification including diet and physical activity, results in weight loss in obese adults when used for six months to one year.

8. **Surgical Interventions** in adults with a BMI $\geq$ 40 or a BMI $\geq$ 35 with co-morbid conditions result in substantial weight loss.

- Five years later, in December 2003, the U.S. Preventive Services Task Force (USPSTF) issued a statement entitled, "Recommendations and Rationale: Screening for Obesity in Adults." This document, which is supported by the Agency for Healthcare Research and Quality (AHRQ), is based on the USPSTF's rigorous examination of scientific evidence specific to overweight and obesity in adults. The USPSTF provides the following recommendations and findings:[4]

  1. **Clinicians should screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.** There is fair to good evidence that high-intensity counseling [two or more individual or group sessions per month for at least the first three months]—about diet, exercise, or both—together with behavioral interventions aimed at skill development, motivation, and support strategies, produced modest, sustained weight loss (typically three to five kg. for one year or more) in adults who are obese (BMI $\geq$ 30). Although the USPSTF did not find direct evidence that behavioral interventions lower mortality or morbidity from obesity, they concluded that changes in intermediate outcomes, such as improved glucose metabolism, lipid levels, and blood pressure, from modest weight loss provide indirect evidence of health benefits.

  2. **The evidence is insufficient to recommend for or against the use of moderate-intensity counseling (one intervention/month) or low-intensity (< one intervention/month) together with behavioral interventions to promote sustained weight loss in obese adults.**
  The USPSTF found limited evidence to determine whether moderate- or low-intensity counseling with behavioral interventions produces sustained weight loss in obese (BMI $\geq$ 30) adults. The relevant studies were of fair to good quality but showed mixed results.

[4] "Recommendations and Rationale: Screening for Obesity in Adults," U.S. Preventive Services Task Force (USPSTF), November 2003. http://www.ahrq.gov/clinic/3rduspstf/obesity/obserr.htm

3. **The evidence is insufficient to recommend for or against the use of counseling of any intensity and behavioral interventions to promote weight loss in overweight adults.** The USPSTF found limited data that addressed the efficacy of counseling-based interventions in overweight adults (BMI from 25 to 29.9). As a result, the USPSTF could not determine the balance of benefits and potential harms of counseling to promote sustained weight loss in overweight adults.

4. **Maintenance of a normal weight is important in addressing the obesity problem.** Life-long habits for nutrition and physical activity must be established. The key element for prevention is caloric balance. Diets should include all food groups, daily portions of fruits and vegetables, low-fat content, and reasonable serving sizes. Physical activity goals should focus on moderate daily exercise or other activity for at least 30 minutes most days of the week.

5. **The most effective interventions combine nutrition education and diet and exercise counseling with behavioral strategies to help patients acquire the skills and supports needed to change eating patterns and to become physically active.** The 5-A framework (Assess, Advise, Agree, Assist, and Arrange) has been used in behavioral counseling interventions such as smoking cessation and may be a useful tool to help clinicians guide interventions for weight loss. Initial interventions paired with maintenance interventions help ensure that weight loss will be sustained over time.

6. **It is advisable to refer obese patients to programs that offer intensive counseling [i.e. two or more individual or group sessions per month for at least the first three months] and behavioral interventions for optimal weight loss.** There are limited data on the best place for these interventions to occur and on the composition of the multidisciplinary team that should deliver high-intensity interventions.

7. **Data for sibutramine and orlistat suggest that these drugs have modest, but potentially sustained effects.** Although average weight loss was consistently modest (weight reduction of 3-5 kg), the percentage of patients achieving clinically significant weight loss (5-10 percent of body weight) was sometimes substantial. Side effects are frequent. Prolonged pharmacotherapy confers some benefit, but its discontinuation may lead to rapid weight regain. There are no data on the long-term (longer than 2 years) benefits or adverse effects of these drugs. Experts recommend that pharmacological treatment of obesity be used only as part of a program that also includes lifestyle modification interventions, such as intensive diet and/or exercise counseling and behavioral interventions.

8. **Clinical guidelines developed by the National Heart, Lung, and Blood Institute (NHLBI) Expert Panel on the identification, evaluation, and treatment of overweight and obesity in adults recommend surgical intervention only for those people with a BMI > 40 or a BMI of 35 to 40**

with at least one obesity-related co- morbidity. The degree of weight reduction obtained with surgical intervention is consistently dramatic (typically 20 kg or more). Based on a large literature of controlled and uncontrolled cohort studies, the weight loss may be prolonged and can be achieved in patients who have multiple co-morbidities. The long-term health effects of surgery for obesity are not well characterized.

- Research published in 2004 continues to support the contention that bariatric surgery is the most effective intervention available to treat severe obesity:

  1. "Pharmacological and Surgical Treatment of Obesity" is a review by the Agency for Healthcare Research and Quality (AHRQ) in July 2004 of the available evidence comparing the relative effectiveness of these types of interventions for obesity. This report concludes that the weight loss attributable to medications is modest (less than five kg. per year), but still may be clinically significant. The article notes that surgical treatment is more effective than nonsurgical treatment for weight loss and the control of some comorbidities. Finally, AHRQ states, "The existing literature is almost bereft of data regarding either pharmaceutical or surgical treatment of adolescent and pediatric patients."[5]

  2. Similarly, research published in the October 13, 2004 JAMA by Henry Buchwald et al., described diet therapy and pharmaceutical agents as ineffective in treating morbid obesity and concluded, "Effective weight loss was achieved in morbidly obese patients after undergoing bariatric surgery. A substantial majority of patients with diabetes, hyperlibidemia, hypertension, and obstructive sleep apnea experienced complete resolution or improvement."[6]

  3. Finally, in November 2004, the Medicare Coverage Advisory committee (MCAC) reviewed current evidence, including the articles outlined above. They concluded that a significant amount of scientific evidence supports the safety and effectiveness of open and laparoscopic weight loss surgery and its ability to improve obesity-related conditions such as diabetes, high blood pressure and high cholesterol in the general adult population. They also noted that more research is needed regarding people 65 and older.[7]

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[5] Shekelle PG, Morton SC, Maglione M, et al. "Pharmacological and Surgical Treatment of Obesity," Summary, Evidence Report / Technology Assessment: No. 103. Agency for Healthcare Research and Quality (AHRQ), Publication Number 04-E028-1, July 2004, p. 5.

[6] Buchwald H, Avidor Y, Braunwald E, et al., "Bariatric Surgery: A Systemic Review and Meta-Analysis," *JAMA*, October 13, 2004, Vol. 292, No. 14:1724-1737, p. 1724.

[7] Newswire, "Medicare Advisory Panel Concludes Weight Loss Surgery Safe and Effective for Morbidly Obese Patients," Baltimore, November 5, 2004.