Report and Recommendations of the Bariatric Work Group

October 2005

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New Jersey Department of Health and Senior Services

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Executive Summary

Obesity is a widespread and growing health problem in the United States. Nearly two out of every three U.S. adults are overweight and at increased risk for chronic medical conditions ranging from type-2 diabetes and coronary artery disease to sleep apnea and many forms of cancer. American employers pay an estimated $13 billion per year in health insurance costs related to obesity. In New Jersey, along with the rising prevalence of obesity, there also has been a 640 percent increase in the number of bariatric, or weight reduction, surgeries between 1999 and 2003. This 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 caused the Department of Health and Senior Services (Department) to form a Work Group comprised of bariatric surgeons, provider associations, physicians representing payers, and consumer advocates. The Work Group's charge was to discuss the following questions:

1. What data is currently available on bariatric surgery in NJ, and whether this data is adequate or needs enhancement;
2. What are the appropriate indications of medical necessity for various types of bariatric surgery;
3. What are the core elements of a good, comprehensive program;
4. What are the professional competencies and training essential to a successful bariatric surgery program;
5. Whether there is a volume/quality association for bariatric surgery;
6. Whether there are agreed-upon standards for assessing the quality of bariatric surgery programs; and
7. What the typical complications associated with bariatric surgery are, and whether there are best practices that reduce the risks of these complications as well as mortality.

This paper is the culmination of the group's thorough and multi-faceted discussions.

Although various factors contribute to obesity, the bottom line is that people become overweight and obese due to an imbalance in the amount of calories consumed and the amount of calories burned. Since 1998, the percentage of New Jersey's population that is overweight, based on the body mass index (BMI), has been slightly higher than the national percentage. The percentage who are obese has been slightly lower than the national number. In both the nation and New Jersey, the obese population has been increasing at a faster rate than the overweight population.

The prevention of obesity is a health priority. Such prevention 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. Prevention of overweight in children and throughout the lifespan is critical. The State recently established by law the Obesity Prevention Task Force in the Department. This task force is charged with developing a NJ Obesity Action Plan, which will include recommendations for specific actionable measures to support and enhance obesity prevention among NJ residents, particularly children and adolescents.

The clinical consensus on treatments for overweight and their effectiveness is evolving. Recent research indicates that bariatric surgery is the most effective intervention currently available to treat severe obesity. In July 2004, the federal Agency for Healthcare Research and Quality (AHRQ) published a review of obesity research to date and concluded that the findings overall suggest that surgical treatment is more effective than pharmacological treatment for weight loss and the control of some co-morbidities. That same year, a JAMA article concluded that effective weight loss was achieved in morbidly obese patients who underwent bariatric surgery. A substantial majority of patients with diabetes, hyperlipidemia, hypertension, and obstructive sleep apnea experienced complete resolution or improvement. Finally, in November 2004, the Medicare Coverage Advisory Committee concluded that a significant amount of scientific evidence supports the safety and effectiveness of 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.

Bariatric surgery, performed using laparoscopic or open procedures, is restrictive, malabsorptive, or both. All types of bariatric surgery require clinical follow-up, commitment by patients to diet and lifestyle changes, and the ongoing use of nutritional supplements, in order to maintain weight loss and avoid adverse health consequences. The benefits of such surgery include the reduction of risk factors for comorbidities; also reported are: improved mobility and stamina; better mood, self esteem, and interpersonal effectiveness; and lessened self-consciousness. Estimates of mortality within 30 days of surgery vary in the research literature, but generally have been reported at 1% or less. Complications of surgery appear to be frequent, particularly those related to the gastrointestinal tract (17% of cases studied) including reflux, vomiting, and dumping syndrome; nutritional and electrolyte imbalances (17% of cases); and surgical complications (including bleeding, wound infections, and re-operation (19%). According to a group of RAND researchers who conducted a meta-analysis of prior studies, the data on complications do not support strong conclusions, and while some complication rates may be substantial, many of these complications may be minor in severity. The risk of mortality or complications is greater with increased weight or BMI, male gender, increased age, and revisional surgery. While severe medical conditions may increase the

risk of complications, bariatric surgery may help resolve or significantly mitigate some of these same co-morbidities.

Department staff analyzed hospital discharge data to review New Jersey trends in bariatric surgery. Between 1998 and 2003, the volume of bariatric surgery in New Jersey rose from 473 to 4,448 cases, an increase of 840%. In 2004, volume declined to 4,018 cases. Potential reasons for this decline could include decisions by some hospitals and/or surgeons to leave the field, due to increasing malpractice costs, and/or the increasing use of insurance policy riders that exclude or limit coverage for bariatric surgery.

In 2003, thirty-six New Jersey hospitals offered bariatric surgery. Two hospitals accounted for 35 percent of all cases. The in-hospital mortality rate was very low, 0.13%, compared to 0.3% in 2001. However, since the overall number of deaths was small in both years, the difference in mortality rate is not likely to be significant. Thirty-day mortality in 2003 was 0.16%. The Department also classified patients by their severity of illness/risk of death prior to surgery. Over 90 percent of patients had low or moderate severity of illness. All of the deaths occurred among patients with a high or very high risk of mortality.

Hospital charges statewide in 2003 for this surgical procedure were $204 million, with an average case charge of $46,000 and average length of stay of 3.8 days. However, hospital charges do not reflect either the actual costs to the hospital of treatment nor the actual payments hospitals receive. In 2003, the statewide average ratio of hospital net patient revenue to charges was 25.5%, suggesting that actual hospital revenues for bariatric surgery may have been closer to $52 million. The Department has no data on bariatric surgeon charges.

Seventy-nine percent of bariatric surgery patients in 2003 were female, while eighty-six percent ranged in age from 30 to 64. Consistent with this predominant age range, 88% of patients had private insurance, while Medicare accounted for 6.3% of patients, Medicaid 0.4%, and self-pay (including charity care) 1.4%. Note, however, that hospital discharge data does not distinguish Medicaid from commercial HMO products, so that the Medicaid share, representing only fee-for-service cases, is likely understated. The Division of Medical Assistance and Health Services, which administers New Jersey's Medicaid program, reports 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%.

There were 108 surgeons performing bariatric surgery in 2003, six of whom had 160 or more cases each. Over 56% of surgeons performed between one and nine cases in that year. Mortality rates were highest for this low-volume group although, once again, the small number of deaths mandates caution in interpretation.

The Department also looked at the primary diagnoses of bariatric surgery patients readmitted to a New Jersey hospital within 180 days of the initial surgery, and counted each instance of readmission for a diagnosis that appears directly related to bariatric surgery as a complication. Work group members assisted the Department in identifying diagnoses representing probable complications. Statewide, there was a 1.26 percent readmission rate within 30 days and a 13 percent complication rate within 180 days. Within the surgeon volume groups, there was no consistent trend, although the surgeons performing 10 to 19 cases per year had a very high complication rate of 79 percent.

Hospitals were also grouped by volume and examined for mortality rates and readmissions within 30 days. There was no consistent association of mortality with volume, except that none of the seven deaths occurred in hospitals with fewer than 50 cases. Thirty-day readmission rates were lowest for those hospitals doing fewer than ten or more than five hundred cases.

Finally, both providers and insurers noted that the biggest single driver of high costs in bariatric surgery are those few cases where complications occur that do not cause immediate death but require long hospitalizations. These are also the cases that seem to generate extensive publicity. In an effort to provide some indirect indication of the volume of such long-stay cases involving complications, the Department added together all hospital days for the initial admission for bariatric surgery as well as any readmission associated with a directly related complication primary diagnosis, within 180 days of surgery. Ninety-one patients, 2.1 percent, spent between 15 and 138 days in a general hospital following bariatric surgery. Thirty-one of these patients, or 0.7 percent, had stays of 30 to 138 days. These data suggest confirmation of the notion that a small subset of bariatric surgery patients experience severe and costly complications.

The only national standard available to guide the selection of patients for whom bariatric surgery may be appropriate was developed in 1991 by the National Institutes of Health (NIH). The NIH standard includes five criteria: (1) BMI $\geq$40 or BMI $\geq$ 35 in association with major medical co-morbidities; (2) strong desire by the patient for substantial weight loss; (3) acceptable operative risks; (4) a “well-informed and motivated patient” and (5) “failure of other non-surgical approaches to long-term weight loss.” Members of the Work Group accept the NIH standard, but there is considerable variation in interpreting the requirements to try and fail at alternative treatments and for the patient to be informed and motivated. Providers tend to view specific insurer requirements relating to documenting failure of alternatives as “hassles” intended to delay and discourage patients, while insurers, in general, remain cautious about bariatric surgery and want evidence that alternatives will not work for an individual patient. In determining patient level of information and motivation, it is especially important that care be offered in a culturally competent manner. Initially, some providers suggested Medicaid or charity care patients were not well enough informed or motivated to be good candidates for bariatric surgery. They were reminded that New Jersey

law requires hospitals to offer their services without regard to patient ability to pay, so that bariatric surgery must be equally available to low income, Medicaid, or charity care patients who satisfy the NIH guidelines. Most Work Group members agreed that a New Jersey hospital offering bariatric surgery should take responsibility for assuring that the NIH patient selection criteria are being applied appropriately, both to avoid inappropriate surgeries as well as to assure equitable access.

The Work Group recommends that every hospital offering bariatric surgery in New Jersey offer a comprehensive program. The characteristics of a comprehensive program are generally based on the Surgical Review Corporation's (SRC) framework, supplemented by criteria from the Massachusetts Department of Public Health's Expert Panel on Weight Loss Surgery bariatric surgery report, released in 2004. A comprehensive program would be expected to include the following: (1) Institutional commitment to ongoing education and training; (2) Volumes: 125 bariatric surgeries/year for the hospital; 125 cases lifetime for each surgeon; (3) A physician Medical Director for bariatric surgery; (4) Board certification for bariatric surgeons; (5) Availability of specialty staff, including an Advanced Cardiac Life Support (ACLS)-qualified physician on site; (6) Dedicated nurse or physician extenders; (7) Full line of equipment for bariatric patients; (8) Utilization of clinical pathways and orders that facilitate the standardization of perioperative care; (9) Support groups for patients; and (10) Documentation of long-term patient follow-up of at least 75% of bariatric procedures at five years. The Work Group does not recommend mandating separate licensure of bariatric surgery programs at this time. The State will continue to track bariatric surgery and decide if a regulatory approach is necessary in the future.

The Work Group agreed that potential bariatric patients need to carefully consider the possible risks and benefits of bariatric surgery with their physician. Potential bariatric patients also need to evaluate the surgeon they choose and where they will have the surgery performed. To assist consumers in gathering relevant information, the Work Group recommends a check list of questions developed by the New York Health Plan Association in cooperation with providers. Additional comments and suggestions have been added to the list to ensure that potential patients will be well informed to make decisions about bariatric surgery. Furthermore, a generic guide for patients which was developed by the federal Agency for Healthcare Research and Quality (AHRQ), "Improving Health Care Quality: A Guide For Patients and Families," may be found at the following website: www.ahrq.gov/consumer/qntlite/qntlite.htm.

The Work Group could not reach consensus on the issue of insurance coverage for obesity treatments, including bariatric surgery. Providers believe 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. Insurers' approaches are evolving. The Centers for

Medicare and Medicaid Services (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. 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.

Providers would like to have the State mandate coverage, not only for bariatric surgery, but also for ancillary services, including pre- and post-operative counseling, and nutritional supplements to offset adverse impacts of the reduced food absorption the surgery is designed to achieve. Such related services and products are rarely covered by insurance and may pose significant treatment barriers, particularly for lower income patients.

The Work Group was made aware that, 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. They also believe it is inappropriate and inequitable to single out one type of medically necessary surgery for coverage limitations.

The Work Group was unable to bridge the gap between the provider and payer viewpoints on insurance coverage.

Finally, the Work Group noted that considerable clinical research on treatment of obesity is ongoing, and that other types of treatment may emerge that are competitive with bariatric surgery in terms of safety, effectiveness, and costs. In the meantime, it was agreed that the Department should continue to use its hospital discharge data for periodic monitoring of bariatric surgery.

Overview

Obesity is a critical health problem that affects approximately 60 million adult Americans. 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] According to Dr. Jeffrey Koplan, former Director of the Centers for Disease Control and Prevention (CDC), "As a nation, we need to respond as vigorously to this epidemic as we do to an infectious disease epidemic." At a recent national conference on the treatment and prevention of obesity, attendees learned that, in regard to the obesity goals of Healthy People 2010, our nation has moved the right amount—but in the wrong direction.[2]

Obesity is defined as an excessively high amount of body fat in relation to lean body mass. Simply put, people become overweight and obese as a result of an imbalance in the amount of calories consumed and the amount of calories burned. Additional factors that likely contribute to obesity include the following: 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 and supersizing of food portions that reputedly contribute to reduced exercise and/or increased consumption of 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 blood 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.[3] 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 of Medicare and Medicaid Services (CMS) removed language in the Medicare Coverage Issues Manual stating that obesity was not an illness.[4]

The cost of obesity is very high. According to the CDC, obesity is associated with approximately 112,000 deaths each year.[5] Although this number has been subjected to considerable criticism, a floor of 26,000 deaths each year

seems beyond dispute. In addition to morbidity and mortality, people with obesity also suffer from social stigma and workplace discrimination. A recent CDC study estimates that U.S. obesity-attributable medical expenditures reached $75 billion in 2003.[6] 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.[7]

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 cutpoints (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.[8] 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.[9]

Table 1

BMI Cutpoints

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

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.[10] Survey results for the years 2000-2003 (Table 2) show that, overall, the percentage of the population that is overweight in New Jersey is consistently higher than the nationwide average. Conversely, the percentage of New Jersey's population that is obese based on BMI has been slightly lower than the nationwide numbers. In both the nation and New Jersey, the obese population has been increasing at a faster rate than the overweight population.[11]

Table 2

Percentage of Total Overweight and Obese Adult Population By Year and State

2000	DE	**NJ**	NY	PA	Nationwide
Overweight	39.2	**38.3**	39.2	36.4	36.7
Obese	16.6	**18.5**	17.7	21.2	20.1
2001					
Overweight	38.4	**38.1**	35.7	38.3	37.2
Obese	20.8	**19.6**	20.3	22.1	21.0
2002					
Overweight	36.2	**37.3**	36.7	35.6	37.0
Obese	22.4	**19.0**	20.6	23.9	22.2
2003					
Overweight	36.2	**37.2**	35.3	36.3	36.7
Obese	24.0	**20.1**	20.9	23.8	22.8

Overweight BMI: 25.0-29.9
Obese BMI: ≥ 30.0

Source: BRFSS

As the percentage of overweight and obese Americans has risen, so too has the volume of surgical treatments for obesity. Table 3 is a comparison of reported bariatric surgery volume in New Jersey, Pennsylvania, and Massachusetts from 1999 to 2003 derived from hospital discharge data. Note that reports on each state employ slightly differing methodologies for identifying bariatric surgery cases and are, therefore, not strictly comparable. However, the key point is the rapid growth in the annual volume of such surgeries in all three states. Between 1999 and 2003, volume increased 640 percent in New Jersey, 360 percent in Massachusetts, and 908 percent in Pennsylvania. This rate of increase far exceeds the rate of growth in obesity, and indicates the increasing acceptability of this treatment modality. New Jersey data indicates a decline from 4,448 cases in 2003 to 4,018 cases in 2004. Newer Pennsylvania and Massachusetts data is not available.

Table 3

Bariatric Surgery Volume by Year and State

Year	NJ*	% Increase	MA**	% Increase	PA***	% Increase
1999	601	NA	600	NA	674	NA
2000	1088	81	1000	67	1315	95
2001	1942	78	1550	55	2684	104
2002	3185	64	1950	26	4402	64
2003	4448	40	2761	42	6791	54
2004	3919	(12)				

Sources: *UB-92 Data. New Jersey
**Commonwealth of Massachusetts Betsy Lehman Center for Patient Safety and Medical Error Reduction Expert Panel on Weight Loss Surgery. Executive Report. Massachusetts Department of Public Health. August 4, 2004.
*** "Obesity Related Surgery in Pennsylvania," PHC4 Research Briefs, Issue No. 2, August 2004.

In August 2004, recognizing the rapid growth of this type of surgery, a seeming increase in the number of hospitals offering bariatric surgery, and a few well-publicized cases of serious complications or death following bariatric surgery, the Department of Health and Senior Services (Department) convened a Bariatric Work Group to review the following bariatric surgery issues:

1. What data is currently available on bariatric surgery in NJ, and whether this data is adequate or needs enhancement;
2. What are the appropriate indications of medical necessity for various types of bariatric surgery;
3. What are the core elements of a good, comprehensive program;
4. What are the professional competencies and training essential to a successful bariatric surgery program;
5. Whether there is a volume/quality association for bariatric surgery;
6. Whether there are agreed-upon standards for assessing the quality of bariatric surgery programs; and
7. What the typical complications associated with bariatric surgery are, and whether there are best practices that reduce the risks of these complications as well as mortality.

Preventing Obesity

At any given time, about 29 percent of men in the United States and 44 percent of women are attempting to lose weight—but only 20 percent report that they are reducing calories or engaging in physical activity to achieve weight loss.[12] 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.[13]

According to the NIH, prevention of 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.[14] The NIH also says 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.

A useful framework for prevention and treatment modalities (Table 4) has been developed by Kaiser Permanente, a large health management organization. Recommended prevention / treatment options, based on risk, are as follows:[15]

Table 4

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

Prevention of overweight in children is especially important. Research shows that about one-third of overweight preschool children and one-half of overweight school age children remain overweight as adults.[16] 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. Among other things, it found that while 60 percent of sixth graders in New Jersey are of normal weight, eighteen percent are overweight and another twenty percent are obese.[17]

It is essential that children and their families learn about and practice obesity prevention together and throughout the lifespan.

Studies have shown that losing even small amounts of weight is beneficial. 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.[18]

Kaiser Permanente also offers a useful longitudinal approach to preventing obesity :[19]

Table 5

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

The State of New Jersey recently established by law (P.L. 2004, Chapter 303) an Obesity Prevention Task Force in the Department.[20] The task force consists 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 is charged with developing a New Jersey Obesity Action Plan, which will include recommendations for specific actionable measures to support and enhance obesity prevention among State residents, particularly children and adolescents. The group is to report its findings and recommendations to the Governor and Legislature no later than eighteen months after the initial meeting of the task force, which occurred on December 20, 2004.

In creating the Obesity Action Plan, the Task Force is to consider components such as the following:

1. Development of a media health promotion campaign targeted to children and adolescents and their parents and caregivers;
2. Establishment of school-based childhood obesity prevention nutrition education and physical activity programs;

3. Establishment of community-based childhood obesity prevention nutrition education and physical activity programs that involve parents and caregivers;
4. Coordination of State efforts with those of federal and local government agencies to incorporate strategies to prevent and reduce childhood obesity into food assistance, health, education and recreation programs;
5. Sponsorship of periodic conferences to bring together experts in nutrition, exercise, public health, mental health, education, parenting, media, food marketing, food security, agriculture, community planning and other disciplines to consider societal solutions to the problem of obesity in children and adolescents and issue guidelines and recommendations for public policy in New Jersey;
6. Development of training programs for health care professionals; and
7. Development of, and support for, community-based projects targeted to high-risk populations.

Evolving Consensus On Treatments For Overweight and Their Effectiveness

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.

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."[21] According to this report:

1. **Low-calorie diets (LCDs)** can reduce total body weight by an average of 8 percent over 3 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 effect a decrease in abdominal fat. As stated on page 2, 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 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 Health 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:[22]

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.

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."[23]

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."[24]

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.[25]

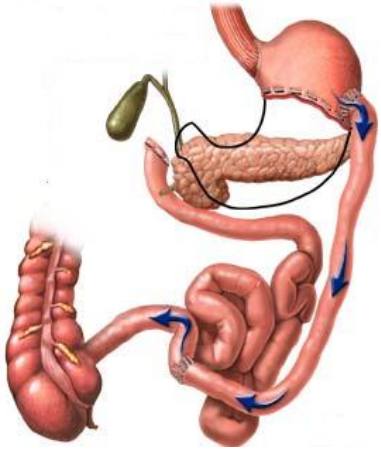
Bariatric Surgery--Overview

Bariatric surgery is performed 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:

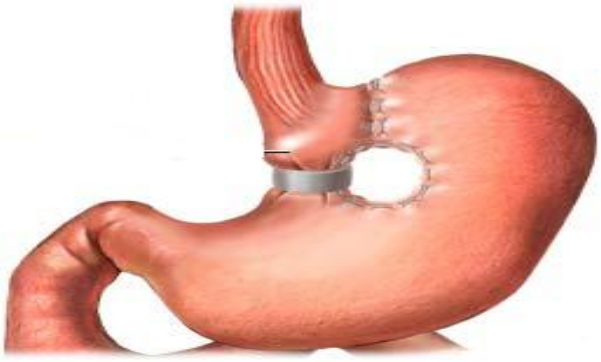
(1) Roux-en-Y Bariatric (RYGB), the most commonly performed weight loss surgery in the United States, has both restrictive and malabsorptive components. This procedure creates a small pouch from the original stomach. The pouch remains attached at one end to the lower part of the esophagus and, at the 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 below.) 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.

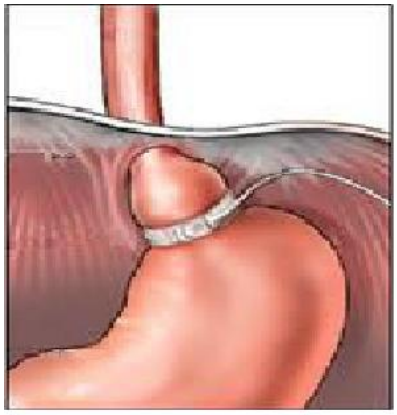
(2) Biliopancreatic Diversion (BPD) is a malabsorptive operation in which portions of the stomach are removed. The small pouch that remains is connected to the final segment of the small intestine which completely bypasses the first two sections of small intestine. This procedure is used less frequently 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.



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.

According to a meta-analysis of the research on bariatric surgery (Table 6), conducted by Maggard, et al, from the RAND Corporation, the following rates of complications, or post-operative adverse events were noted:

Table 6

Postoperative Adverse Events by Bariatric Procedure*

Procedure	GI Symptoms, All**		Reflux		Vomiting		Nutritional & Electrolyte Abnormalities***		Surgical, Preventable and Not Preventable^	
	Adverse Events, %	Studies/ Patients, n/n	Adverse Events, %	Studies/ Patients, n/n	Adverse Events, %	Studies/ Patients, n/n	Adverse Events, %	Studies/ Patients, n/n	Adverse Events, %	Studies/ Patients, n/n
RYGB	16.9	34/7374	10.9	3/727	15.7	8/1324	16.9	10/2088	18.7	49/10088
VBG	17.5	21/1692	2.2	7/823	18.4	10/1177	2.5	4/397	23.7	34/3247
Adjustable gastric banding	7.0	17/3400	4.7	4/485	2.2	4/562	NR	0/0	13.2	34/8846
BPD	37.7	1/305	NR	0/0	5.9	1/305	NR	0/0	5.9	5/2663

"Meta-Analysis: Surgical Treatment of Obesity," Maggard, MA, et. al., *Annals of Internal Medicine,* April 15, 2005, Vol. 142, No. 7: 547-559, p.554.

*Seventy trials of RYGB, 48 trials of VBG, 41 trials of adjustable gastric banding, and 7 trials of BPD were considered for analysis by procedure.

BPD=biliopancreatic diversion; GI=gastrointestinal; NR=not reported; RYGB=Roux-en-Y gastric bypass; VBG=vertical banded gastroplasty.

**Including reflux, vomiting, dysphagia, dumping syndrome, and others.

***Including mineral, vitamin, and protein deficiencies

^Including anastomotic, stoma-related, bleeding, reoperation, wound, and others.

Maggard et al. suggest that the data on adverse events do not support strong conclusions. They go on to say, "The absolute rates of some complications are substantial, although many may be minor in severity."[26]

While the above table is based on reputable studies, there is no standard national reporting and classification system regarding the complications of bariatric surgery, so caution must be used in taking this data at face value. The Buchwald article cited earlier states, "Complication rates were difficult to catalog because they were variably reported, dependent on duration of follow-up, and were procedure specific, as well as a function of open compared to laparoscopic technique."[27] As a result, Buchwald declined to include complication rates.

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.[28]

While severe medical conditions may increase the risk of complications, bariatric surgery may help resolve or significantly mitigate some of these same co-morbidities. The previously cited article by Buchwald et, al. documented that a substantial majority of patients with specified co-morbidities experienced complete resolution or improvement following bariatric surgery. According to Buchwald, strong evidence was found for the improvement of type 2 diabetes and impaired glucose intolerance following bariatric surgery. In addition, the study noted that hyperlipidemia, hypertension, and obstructive sleep apnea were all significantly improved following bariatric surgery.[29]

Although the Work Group was charged with assessing best surgical techniques and post-operative practices to reduce complications and mortality, no recommendations are being made. Work Group members, particularly the surgeons, felt strongly that, absent the development of detailed practice guidelines for bariatric surgery by any national certifying boards, there is no sound basis for the Work Group to make formal recommendations on best surgical practices.

Analysis of 2003 Uniform Billing Data on Bariatric Surgery in New Jersey

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 includes an extensive amount of demographic and clinical data, including up to one primary and eight secondary diagnosis codes (scheduled to be expanded to a total of 17 codes in 2007), as well as procedure codes. It utilizes 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. UB data 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 the data of interest to researchers. Additionally, since some data fields on the form are of less interest to insurers than to researchers, the reliability of data on a UB form is not uniform. UB data is not audited, and its accuracy has well-known limitations. Nevertheless, UB data is frequently used in health services research, because it is readily available in many states and provides sufficient volume for statistical analysis.

At this time, UB data is the only source of information on bariatric surgery cases in New Jersey. In the course of the Work Group's discussions, the Department discovered that there is no single diagnosis or procedure code which corresponds to bariatric surgery. The Work Group reviewed efforts in Massachusetts, New York, and Pennsylvania to use their UB data to measure growth in bariatric surgery and consulted with payer representatives on the Work Group. This process resulted in an approach that combines primary diagnosis

with procedure codes also found in the UB data to identify likely bariatric surgery cases.

1. Diagnosis and Procedure Codes Selected

Diagnosis Codes Used are:

- 278 – obesity and other hyperalimentation
- 278.01 – morbid obesity

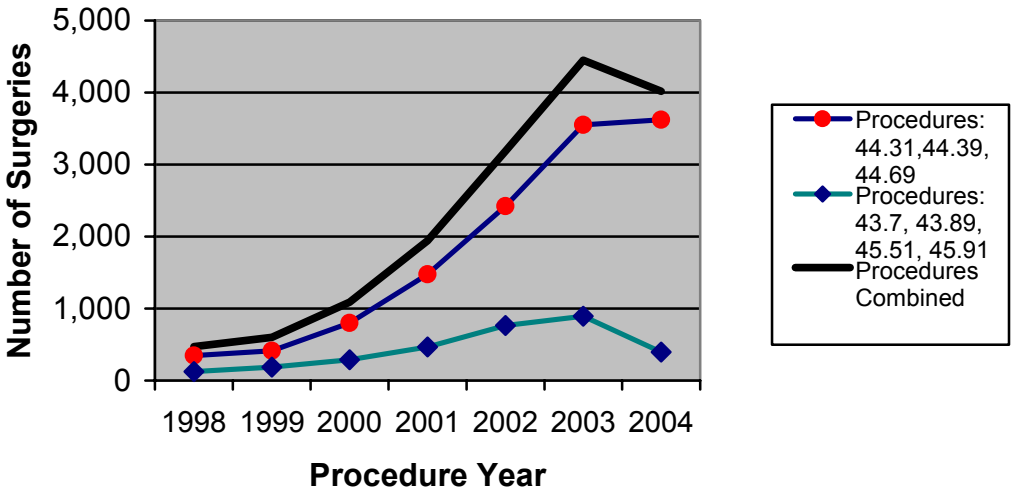
Procedure Codes Used are:

- 43.7 – partial gastrectomy with anastomosis to jejunum
- 43.89 – other partial gastrectomy
- 44.31 – high gastric bypass
- 44.39 – other gastroenterostomy
- 44.69 – repair stomach NOS
- 45.51 – isolate segment small intestine
- 45.91 – small to small intestinal anastomosis

2. Volume Trends in Bariatric Surgery

Pennsylvania and Massachusetts are the only other states that have published data on bariatric surgery, and they also employ UB data, albeit slightly different code combinations. In Massachusetts, the number of bariatric surgeries performed was about 600 in 1999. In 2003, the number had increased to 2,761 – an increase of over 400 percent. Pennsylvania also experienced dramatic growth of bariatric surgeries between 1999 and 2003, from 674 surgeries to 6,791, more than ten-fold growth. Similar to trends in these states, bariatric surgery in New Jersey has increased dramatically over the past few years. According to the 1998 UB data, there were only 473 bariatric surgery procedures statewide. There were 4,448 cases in 2003, an increase of 840 percent between 1998 and 2003. However, in 2004, there were 4,018 bariatric surgeries performed, a decrease of about 10 percent from 2003. The reasons for the decline are unknown, but may reflect decisions by hospitals and/or surgeons to leave the field due to malpractice costs and/or increasing use of limitations or coverage exclusions by insurers/payers.

Figure 1. Recent Trends in Bariatric Surgeries



3. 2003 Bariatric Surgery Mortality

In the 2003 UB data, a total of 4,448 bariatric surgeries were performed by 36 hospitals in New Jersey. Initially, there were 51 hospitals which appeared to be performing bariatric surgery for a total of 4,470 cases. DHSS contacted all hospitals with fewer than five bariatric cases to determine if these were coding errors. This process resulted in removing 15 hospitals and 22 cases from the analysis. The mortality rate from bariatric surgery is very low. There were six in-hospital deaths during the stay when the bariatric surgery was performed, resulting in an in-hospital mortality rate of 0.13%. The Work Group also looked at mortality thirty days after surgery. In order to do this in cases where death occurred after the initial discharge, Department staff looked for any other UB record for the same patient showing a death up to thirty days after the initial admission. For analytical purposes, the subsequent record was linked to the initial hospital and surgery, not only to determine mortality rates, but also 30-day readmission and 180-day complication rates and total days in hospital. Analysis of the 2003 UB data for 30-day mortality showed one additional death, raising the mortality rate to 0.16% (Table 7).

This approach has limitations: it cannot account for deaths or readmissions that occurred outside a New Jersey general hospital. Therefore, in an attempt to validate the bariatric surgery mortality rate obtained from analysis of the UB data alone, we compared the 2001 mortality rate derived from the UB data (n=1,957) with the rate resulting from linking UB and death records maintained by the Department's Center for Health Statistics. Data from 2001 was chosen because

the death file for that year is complete. Due to the length of time required to complete the death registry file for a given year, it is not possible to perform a cross-match of the latest UB data with death records. UB data are typically available six months after the end of the calendar year. Death files, on the other hand, may take two years or longer to complete, in part due to the necessity of exchanging data with New York and Pennsylvania to obtain records regarding the mortality status of New Jersey residents.

The in-hospital mortality rate in 2001 was 0.31%. All bariatric surgery patients who received the procedure in 2001 were followed within the UB system for subsequent admissions to any New Jersey hospital to measure the 30-day bariatric surgery mortality rate. The 30-day bariatric surgery mortality rate was estimated to be 0.56% or 11 deaths. As stated, this approach misses all deaths that did not occur in a hospital, (e.g. patients may have transferred to a nursing home or home), or within a hospital located in New Jersey. To determine the size of this potential gap, we then matched initial bariatric surgeries identified in the UB data to NJ death records. Since the UB data include no social security number, this match was an approximation, using name, gender and date of birth. The resulting 30-day mortality rate using this approach was 0.72% or 14 deaths, only three more than relying solely on UB data. While the rates from the two approaches differ, it is important to note that the number of deaths was very small in both instances. The Work Group concluded that use of UB data only in order to analyze 30-day mortality trends in more recent years could yield useful, if not entirely accurate data.

Table 7

Bariatric Surgery Mortality Rates in New Jersey, 2001 and 2003

	2001		2003	
Bariatric Surgery Deaths	**Number**	**Death Rate (%)**	**Number**	**Death Rate (%)**
Initial Bariatric Deaths	6	0.31	6	0.13
Within UB Deaths 30 days after Surgery	11	0.56	7	0.16
Deaths After Matching with Death Records*	14	0.72	-	-

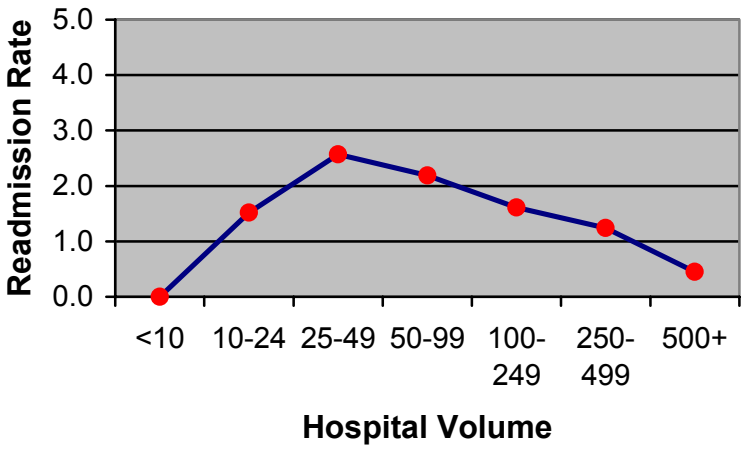
Note: The death rates were derived from bariatric surgeries reported in the 2001 and 2003 UB data.

* No UB-to-death matching was performed on 2003 UB data because of incomplete death records at the time of analysis.

4. 2003 Bariatric Surgery Readmissions

The quality of bariatric surgery, indicated by patient readmission rates, appears to have improved over the past few years. The 30-day readmission rate declined from 2.3% in 2001 to 1.26% in 2003. Even though this decline is not statistically significant, it suggests a decline of almost 45% over the two-year period. The 2003 readmission data was examined in relation to hospital case volume; no clear pattern emerged, but lower volume hospitals with 10 to 25 cases had higher readmission rates than either very low or high volume hospitals (Figure 2).

Figure 2. 30-Day Readmission Rates by Hospital Volume, 2003



5. 2003 Bariatric Surgery Hospital Charges

Hospital charges statewide for bariatric surgeries in 2003 were $204 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 $46,000, while the average length of stay was 3.8 days. 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 2003, the statewide average ratio of hospital net patient service revenue to charges was 25.5%, suggesting that the total amount of revenue actually collected by hospitals may have been closer to $52.0 million (25.5% x $204 million).

6. 2003 Bariatric Surgery Patient Characteristics

As indicated earlier, there were 4,448 bariatric surgeries reported in the 2003 UB data. Bariatric surgery patients in age group 35-39 represented the largest group of patients, accounting for 16.5 percent of all bariatric surgeries, followed closely by those who were 40-44 years old (15.5%), and 45-49 years old (15.4%). Nearly 80 percent (79.0%) of bariatric surgery patients were female. Almost 88 percent of the patients paid for the bariatric surgery procedure through private insurance providers, with Medicare paying for only 6.3 percent, and Medicaid only 0.4 percent. It should be noted, however, that UB data does 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 shows only Medicaid fee-for-service patients and likely understates Medicaid's share of bariatric surgery patients. The Division of Medical Assistance and Health Services, which administers New Jersey's Medicaid program, reports 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%.

Table 8

Bariatric Surgery Patient Characteristics

Age Group	Total	Column %
15-19	48	1.1
20-24	144	3.2
25-29	348	7.8
30-34	555	12.5
35-39	733	16.5
40-44	691	15.5
45-49	683	15.4
50-54	600	13.5
55-59	401	9.0
60-64	171	3.8
65-69	63	1.4
70+	11	0.2
Total	**4,448**	**100.0**
Sex		
Female	3,514	79.0
Male	934	21.0
Total	**4,448**	**100.0**
Payer		
Medicare	281	6.3
Medicaid FFS	16	0.4
Private	3,910	87.9
Self Pay	64	1.4
Other	177	4.0
Total	**4,448**	**100.0**

Source: New Jersey 2003 and 2004 UB data.

Note: UB data does not distinguish Medicaid HMOs from other HMOs. However, the Division of Medical Assistance and Health Services reports that there were 114 gastric bypass surgeries for Medicaid clients covered by Medicaid HMOs.

7. 2003 Bariatric Surgery Data by Hospital

Because of the small volume of bariatric surgeries reported in some hospitals, the Department contacted all hospitals that reported fewer than five cases to determine if they are really performing bariatric surgeries or whether these cases were anomalies resulting from coding errors. Response from these hospitals indicated that they did not perform any bariatric surgeries in 2003. These hospitals were, therefore, deleted from the analysis. This resulted in 36 hospitals in New Jersey that were identified as performing bariatric surgery in 2003.

Two hospitals accounted for a third (34.9%) of all the bariatric surgeries while four hospitals performed 51 percent of all bariatric surgeries. The readmission rates within 30 days of initial bariatric procedures varied by hospital, ranging from 0.0% to 9.1% (Appendix Table 2). The summary of hospitals broken down by volume for initial bariatric procedures and readmissions within 30 days, in-hospital and 30-day mortality is shown in Table 9. There was no consistent association of mortality with volume, except that none of the deaths occurred in hospitals with fewer than 50 cases. Thirty-day readmission rates were lowest for those hospitals doing fewer than ten or more than five hundred cases. Readmission rates were calculated by looking at the primary diagnoses of bariatric surgery patients readmitted to a New Jersey hospital within 30 days of the initial admission, where the primary diagnosis was for a directly related complication of bariatric surgery. Each such readmission was counted. Work Group members assisted the Department in identifying diagnoses representing probable complications. (See Appendix Table 8 for a list of the diagnosis codes tracked for complication and readmission rates.)

Table 9

Bariatric Procedures by Hospital Volume, 2003

Hospital Volume	Number of Hospitals	Initial Bariatric Procedures	Readmission Within 30 Days		In-Hospital Mortality		30-Day Mortality	
			N	Rate (%)	N	Rate (%)	N	Rate (%)
>500/year	2	1,554	7	0.45	2	0.13	2	0.13
250 - 499	2	728	9	1.24	0	0.00	0	0.00
100 - 249	8	1,246	20	1.61	3	0.24	3	0.24
50 – 99	7	549	12	2.19	1	0.18	2	0.36
25 – 49	7	272	7	2.57	0	0.00	0	0.00
10 – 24	4	66	1	1.52	0	0.00	0	0.00
<10	6	33	0	0.00	0	0.00	0	0.00
TOTAL	**36**	**4,448**	**56**	**1.26**	**6**	**0.13**	**7**	**0.16**

Source: New Jersey 2003 UB Data.

8. 2003 Bariatric Surgery by Surgeon

Of the 108 surgeons who performed bariatric surgeries in 2003, six had volumes of 160 or more each. Ten surgeons performed 100-159 cases. Over 56 percent of the surgeons (61 out of 108) performed between 1-9 cases in 2003.

Mortality rates among the surgeon volume groups were almost identical for both initial hospitalization and deaths 30 days after bariatric admissions. There was one extra death 30 days after admission. Mortality rates were highest for surgeons performing one to nine cases, followed by those doing ten to nineteen cases. Thereafter, there was no consistent volume-mortality correlation. Moreover, the overall number of deaths was so low that caution must be used in interpreting this data.

As stated above, in consultation with Work Group members, Department staff identified directly related complications from primary and secondary diagnosis codes reported on the UB on readmitted patients. Staff then searched for the number of such complication codes among all diagnosis codes for each readmission of patients within 180 days after initial admission for bariatric surgery. The Work Group was interested in capturing the full range of complications arising from bariatric surgery. Such complications for a readmitted patient may be reported either as a primary diagnosis or under one or more of the eight secondary diagnoses 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 on Table 10.

Overall in 2003, there were 586 directly related complications within 180 days of the bariatric procedure among the 4,448 bariatric surgery patients. This represents a 13.1 percent complication rate within 180 days of the procedure.

Complication rates were highest among the 10-19 case volume surgeon group (Table 10). The complication rate for this group of surgeons was 77.9 percent. The next highest complication rate was 23.4 percent and was associated with surgeons who performed 20-49 cases a year. The lowest complication rate of 4.7 percent was among surgeons performing 50-99 cases a year.

Table 10

Surgeon and Patient Distribution by Surgeon Volume, 2003

Surgeon Volume Group	Number of Surgeons	Number of Patients*	Initial Hospitalization Mortality		Deaths 30 Days After Bariatric Admission*		Directly Related Complications** - (Readmissions Within 180 Days***)	
			Number	Death Rate (%)	Number	Death Rate (%)	Total Number of Complications	Complications Rate (%)
1-9	61	119	2	1.68	2	1.68	8	6.61
10-19	7	103	1	0.97	1	0.97	81	77.88
20-49	11	394	0	0.00	0	0.00	92	23.35
50-99	13	889	0	0.00	0	0.00	42	4.69
100-159	10	1,291	0	0.00	1	0.08	121	9.34
160+	6	1,652	3	0.18	3	0.18	242	14.61
Total	**108**	**4,448**	**6**	**0.13**	**7**	**0.16**	**586**	**13.12**

Source: New Jersey 2003 and 2004 UB data.

* = 1 Additional death was identified after follow-up of patients within the UB system.

** = See Appendix Table 8 for the list of directly related complications.

*** = Includes 18 cases discharged in 2004.

9. Severity of Illness and Risk of Mortality

Appendix Tables 3 through 6 present bariatric surgery patients by severity of illness and by risk of mortality using 3-M's proprietary system for risk-adjusting UB data. The APR-DRG grouper 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.

The statistics in Appendix Tables 3 and 5 show that, for more than 90% of the total statewide bariatric surgery patients, the severity of illness was either low or moderate. All six initial bariatric surgery deaths occurred among patients who scored "very high" both on severity of illness and risk of mortality indicators (Tables 3 and 4).

10. Length of Hospital Stay(s)

The Department added together all hospital days for the initial hospital stay during the bariatric surgery and for any subsequent admission with primary or secondary diagnoses of a complication directly related to bariatric surgery within 180 days of the surgery. In order to capture length of hospital stay by 2003 bariatric surgery patients 180 days after admission, staff used data from 2004 to follow patients who had bariatric surgery in the latter part of 2003. Since the data is attributed to the year of discharge, an additional 18 patients were identified who were discharged in 2004.

Almost 48 percent of patients averaged 3–4 days in hospital, while 36.7 percent stayed for two days or less. Together, about every four out of five bariatric patients (84.5 percent) stayed 1 to 4 days. There were 544 patients (12.2 percent) who stayed for 5-9 days and 55 patients (1.2 percent) who spent an average of 15–19 days in a hospital. Ninety one patients, 2.1 percent, spent between 15 and 138 days in a general hospital either during their bariatric surgery admission or a subsequent admission. Thirty one of these patients, 0.7 percent, had stays of 30-138 days. The data suggest confirmation of the perception that there is a small subset of bariatric surgery patients who experience severe and costly complications (Table 11).

Table 11

Distribution of Statewide Bariatric Surgery Patients by Length of Hospital Stay in Days

Length of Hospital Stay in Days*	Number of Patients**	Percent
<=2	1,641	36.7
3-4	2,135	47.8
5-9	544	12.2
10-14	55	1.2
15-19	37	0.8
20-24	16	0.4
25-29	7	0.2
30-49	19	0.4
50-79	5	0.1
80-138	7	0.2
Total	**4,466**	**100.0**

Source: New Jersey 2003 and 2004 UB Data

Notes:

* Total days for the initial admission as well as for each directly-related readmission to any New Jersey general hospital 180 days after bariatric surgery.

** Includes 18 cases who were admitted in 2003 but were discharged in 2004.

State Bariatric Surgery Registry vs. Uniform Billing Data

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 currently maintains patient-level registries on all births, as well as all cardiac catheterization and cardiac surgical procedures, among others. Registries are labor-intensive and expensive for both hospitals and the Department to maintain. Use of registry data, as in the Department's cardiac surgery performance report, also requires audits, which are time-consuming and costly.

At this time, the Work Group does not recommend creation of a State bariatric surgery registry. The SRC and the American College of Surgeons are each planning to establish private registries. The Department and Work Group do not wish to pursue a state registry while there is a lack of consensus in the field about standardized registry data elements. In addition, the Department does not have the fiscal resources to develop a registry. The Work Group was also cognizant of the fiscal burden on hospitals of mandating registry reporting. Cardiac surgery hospitals in New Jersey estimate an annual cost of $100,000 to report data to the Department's open heart registry. For the time being, therefore, the Department will rely upon UB data, supplemented where possible by death record files, etc. However, the registry question warrants revisiting in the future.

Patient Selection

In the absence of any other national standard, the Work Group agreed that the patient selection guidelines from the 1991 National Institutes of Health (NIH) Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity[30] should serve as the basis for selecting candidates for bariatric surgery. These criteria, paraphrased below, include:

- BMI $\geq$ 40 or BMI $\geq$ 35 in association with major medical complications of obesity (e.g., cardiovascular disease, type 2 diabetes, sleep apnea);
- A well-informed and motivated patient;
- A strong desire for substantial weight loss;
- Failure of other non-surgical approaches to long-term weight loss; and
- Acceptable operative risks.

Some of the criteria, however, are more subjective and open to widely varying interpretations. Group members themselves did not agree on the characteristics of a "well informed and motivated patient" or how one measures "failure of other non-surgical approaches to long-term weight loss."

The Work Group surgeons generally agreed that patients who meet the NIH-recommended BMI criteria should be eligible for bariatric surgery, while payers are interested in seeing documented failures of alternative approaches over some period of time. Surgeons believe the evidence is convincing that a morbidly obese person will not lose weight on other regimens, and that insurers use this criterion to increase barriers to treatment. On the other hand, one representative of a payer would like to see NIH guidelines interpreted such that patients with BMI $\geq$ 35 must have co-morbidities directly related to the weight problem, citing a 2000 article by Balsinger et, al.: "A strictly weight-based definition is not appropriate, however, and a better definition of *morbid obesity* includes patients who have direct, weight-related serious morbidity, such as mechanical arthropathy, hypertension, type 2 diabetes mellitus, lipid-related cardiac disease, and sleep apnea."[31] The Work Group was unable to reach agreement on further refinement of the NIH criteria. Most members, however, agreed that a hospital offering bariatric surgery should take some responsibility for assuring that the NIH patient selection criteria are being applied appropriately and equitably.

Interestingly, when it came to uninsured patients, providers were also concerned about patients being able to satisfy the more subjective criteria. Some suggested that Medicaid and charity care patients are not good candidates for the surgery, since they were seen as not meeting the "well-informed and motivated patient" standard, in addition to being unable to afford to purchase required post-op nutritional supplements. However, the Work Group was vigorously reminded that New Jersey law mandates that a hospital which offers a service, such as bariatric surgery, must ensure that such services are available on an equitable basis to all patients who meet the patient selection criteria, regardless of their ability to pay. New Jersey hospitals and physicians are expected to demonstrate cultural competence in equitably assessing patients.

The Work Group agreed on several practices to increase patient knowledge. All prospective patients should be required to attend an introductory orientation prior to their initial office visit with a surgeon. The orientation would make patients aware of the following: (1) components of the pre-operative evaluation (i.e. medical evaluation; upper endoscopy; gall bladder ultrasound; pulmonary screen; psychological evaluation; and dietary evaluation and education); (2) members of the hospital's weight-loss program team (e.g. Medical Director, surgeon, nurse clinician/hospital program coordinator, registered dietitian, clinical psychologists, and exercise physiologist); and (3) components of post-discharge care (i.e. access to support staff and surgeon, medical follow-up, psychological follow-up if

needed, support group, and buddy). Furthermore, several weeks prior to the surgery, bariatric surgery candidates should be given a tour of the campus where they have a chance to meet with team members.

Characteristics of a Comprehensive Bariatric Surgery Program

The Work Group agreed that hospitals in New Jersey should offer comprehensive bariatric surgery programs rather than simply credential bariatric surgeons to admit patients. In an effort to determine the essential characteristics of a bariatric Center of Excellence, the Work Group compared criteria developed by the SRC and the MA Department of Health Betsy Lehman Center report. The general consensus of the Group was to endorse the SRC framework, supplemented in some cases by the Massachusetts criteria. (It should be noted that endorsement of this framework does not constitute a recommendation for hospitals to seek SRC certification, particularly since other organizations appear to be developing certification standards.) It was agreed that a comprehensive bariatric surgery program should satisfy the following minimum standards.[32]

1. The hospital provides an ongoing, regularly scheduled, in-service education program in bariatric surgery and employs credentialing guidelines for bariatric surgery.

2. The hospital maintains a physician Medical Director for bariatric surgery who is a board-certified bariatric surgeon and who participates in the relevant decision-making administrative meetings of the institution. The Medical Director conducts regularly scheduled meetings that involve medical staff, nursing, operating room, administration, and central supply personnel.

3. The hospital performs at least 125 bariatric surgical cases per year. Each surgeon performs at least 125 total bariatric cases lifetime with at least 50 cases performed in the previous year. 'Bariatric surgical cases' are defined as primary operations, emergency procedures, and/or revisions. 'Performed' is defined as conducting a significant part of the operation.

4. The hospital has a bariatric surgeon who spends a significant amount of time in the field of bariatric surgery and who has qualified coverage for patient care. The surgeon and covering surgeon must be certified by the American Board of Surgery (ABS), American Osteopathic Board of Surgery (AOBS), and/or Royal College of Surgeons of Canada (RCSC).

5. The hospital maintains, within 30 minutes of request, a full complement of staff required to care for bariatric surgical patients,

including the immediate availability of an Advanced Cardiac Life Support (ACLS)-qualified physician on site.

6. The hospital designates nurse and/or physician extenders who are dedicated to serving bariatric surgical patients and who take continuing education classes regarding the care of bariatric patients. The hospital also designates a bariatric coordinator to supervise the bariatric program.

7. The hospital maintains a full line of equipment and instruments used in caring for bariatric surgical patients, including furniture, wheel chairs, operating room tables, beds, radiologic capabilities, and surgical instruments.

8. The hospital uses clinical pathways and orders that facilitate the standardization of perioperative care. The surgeon selects which primary operation(s) to perform and such procedures must be done in a standardized manner. Similarly, the surgeon determines and documents the details of the planned perioperative care. Specific processes are followed so that outcomes can be evaluated. Clinical pathway protocols are available for review during site visits.

9. The hospital makes available organized support groups for all patients who have undergone bariatric surgery at the hospital. Details regarding the groups--such as locations, meeting times, supervisors, and curriculum--are documented.

10. The hospital documents long-term patient follow-up of at least 75% for bariatric procedures at five years. This documentation includes a monitoring and tracking system for outcomes, and agreement to provide annual outcome summaries in a manner consistent with Health Insurance Portability and Accountability Act (HIPAA) regulations.

Although many hospitals have bariatric surgery programs, the Work Group noted gaps in the continuum of care for obesity. After the bariatric surgery is completed, patients often lack essential and appropriate follow-up care. Primary care physicians often send bariatric patients with problems or concerns back to surgeons, some of whom are not qualified to deal with the post-surgical issues of bariatric patients.

The Work Group discussed whether these comprehensive program characteristics should be mandated, either by incorporation into licensure standards or required accreditation by a national accrediting organization. At this time, the Work Group encourages all hospitals which perform bariatric surgery to voluntarily adopt a comprehensive approach. The Department will continue to track bariatric surgery and may revisit this issue in the future.

Consumer Selection of a Bariatric Surgery Program

The Work Group agreed that patients need to carefully consider the potential risks and benefits of bariatric surgery with their physician. Potential bariatric patients also need to carefully evaluate the surgeon they choose and where they will have the surgery performed. To assist consumers in gathering relevant information, the Work Group recommends a check list of questions developed by the New York Health Plan Association in cooperation with providers.[33] Additional comments and suggestions have been added to the list to ensure that potential patients will be well informed to make decisions about bariatric surgery. Furthermore, a generic guide for patients which was developed by the federal Agency for Healthcare Research and Quality (AHRQ), "Improving Health Care Quality: A Guide For Patients and Families," may be found at the following website: www.ahrq.gov/consumer/qntlite/qntlite.htm.

Selection of a Surgeon

1. **What types of bariatric procedures does the surgeon perform?**

    a. "**Open**" surgery involves cutting the skin and tissues so that the surgeon has a full view of the organs involved. "**Laparoscopic**" surgery is performed through multiple small incisions (1/4 to 1/2 inch long). Into these incisions, the surgeon inserts a surgical telescope to view the organs and specially-designed surgical instruments to perform the procedure. Increasing numbers of weight loss surgeries are performed using the less invasive laparoscopic procedures. Such procedures may reduce the likelihood of wound infections, lower post-operative pain, and shorten hospital stays. Nevertheless, they are not risk-free. Discuss the pros and cons of open and laparoscopic surgery in your particular case with your surgeon.

2. **How many bariatric procedures of each type (Open or Laparoscopic) does the surgeon perform per year?**

    a. Ask your surgeon how many procedures s/he has performed in the past year, in which hospitals. As noted in this report, the SRC's criteria for a comprehensive bariatric surgery program (i.e. Center of Excellence) suggests that each surgeon is expected to perform at least 125 total bariatric cases lifetime with at least 50 cases performed in the previous year.

patients should look for a hospital that (1) is accredited by the Joint Commission on Accreditation of Healthcare Organization; (2) is rated highly by the State and by consumer groups or other organizations; (3) is one where your doctor can treat you; (4) is covered by your health plan; (5) has a lot of experience and success with your condition; and (6) monitors quality of care and works to improve quality.

While New Jersey does not rate hospitals specifically on their performance of bariatric surgery, it does publish information rating hospitals for their treatment of other common diseases, i.e., heart attack and pneumonia. The tables in this report also offer further descriptive data on hospitals performing bariatric surgery in New Jersey.

Some of the specific things to ask include:

1. **Does the hospital have staff specially trained to care for bariatric patients?**

2. **How often is the procedure done at this hospital?**

    a. Ask the surgeon or a hospital administrator for this number. According to the SRC criteria cited above, a Center of Excellence is expected to perform at least 125 bariatric surgical cases per year.

3. **Does the anesthesiologist have extensive experience with obese patients?**

    a. Ask the surgeon how many years and how successfully the anesthesiologist has worked with obese patients. Request the anesthesiologist's name and check her/his credentials on the profile described in #3 above.

4. **Does the hospital have specialized bariatric equipment that can accommodate a person of your weight?** (i.e. blood pressure cuffs, CT scanner, hospital bed, wheelchair, gowns, commode, operating room table). Ask to see and try out some of the equipment such as the wheelchair and blood pressure cuffs.

5. **Does the surgeon and/or hospital have a follow-up or after-care program in place?**

    A strong commitment to follow-up care is essential. As noted in this report, post-discharge care should include components such as access

to the surgeon and support staff, medical follow-up, nutritional and exercise follow-up, and psychological follow-up if needed.

6. **Does the surgeon and/or hospital offer patient support groups both pre- and post-surgery?**

   In many cases, patients have greater success losing weight, maintaining weight loss, and dealing with lifestyle changes related to bariatric surgery when they participate in support groups. Ask when and where the groups meet. Are the times and locations convenient for you? Also ask what type of professional will lead the groups. You might want to ask if you could observe a support group meeting and/or speak with other patients who attend such groups.

Insurance Coverage Issues

The Work Group could not reach consensus on the issue of insurance coverage for obesity treatments, including bariatric surgery. Providers believe 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. Insurers' approaches are evolving.

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 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 remains disagreement 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.

Providers would like to have the State mandate coverage, not only for bariatric surgery, but also for ancillary services, including pre- and post-operative counseling, and nutritional supplements to offset adverse impacts of the reduced food absorption the surgery is designed to achieve. Such related services and products are rarely covered by insurance and may pose significant treatment barriers, particularly for lower income patients.

The Work Group was made aware that, 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. They also believe it is inappropriate and inequitable to single out one type of medically necessary surgery for coverage limitations.

The Work Group was unable to bridge the gap between the provider and payer viewpoints on insurance coverage.

Conclusion

Considerable clinical research is occurring 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 Work Group agreed the Department should continue to use its hospital discharge data for periodic monitoring of bariatric surgery and consultation with expert stakeholders.

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APPENDIX

Table 1: BARIATRIC SURGERY TRENDS IN NEW JERSEY, 1998 - 2004

Diagnosis = 278, 278.01

Year	Procdure = 44.31 44.39 44.69	Procdure = 43.7 43.89 45.51 45.91	Combined Total	% Change
1998	347	126	473	-
1999	415	186	601	27.06
2000	799	289	1,088	81.03
2001	1,475	467	1,942	78.49
2002	2,422	763	3,185	64.01
2003	3,553	895	4,448	39.65
2004*	3,543	376	3,919	-11.89

Source: New Jersey Uniform Billing Database 1998-2004.

Note: * 2004 data was not complete at the time of this analysis.

APPENDIX

TABLE 2: BARIATRIC PROCEDURES BY HOSPITAL, 2003

HOSPITAL	INITIAL BARIATRIC PROCEDURES	READMISSION WITHIN 30 DAYS		IN-HOSPITAL MORTALITY		30-DAY MORTALITY	
		N	RATE (%)	N	RATE (%)	N	RATE (%)
Atlantic City Medical Center-City	103	1	0.97	0	0.00	0	0.00
Barnert Hospital	106	1	0.94	0	0.00	0	0.00
Bayonne Medical Center	5	0	0.00	0	0.00	0	0.00
Cathedral-St. Michael's Medical Center	35	3	8.57	0	0.00	0	0.00
Chilton Memorial Hospital	41	0	0.00	0	0.00	0	0.00
Englewood Hospital and Medical Center	97	1	1.03	0	0.00	1	1.03
Hackensack University Medical Center	817	3	0.37	0	0.00	0	0.00
Holy Name Hospital	134	2	1.49	1	0.75	1	0.75
Jersey Shore University Medical Center	55	1	1.82	0	0.00	0	0.00
Kennedy Memorial Hospitals UMC-Stratford	9	0	0.00	0	0.00	0	0.00
Lourdes Medical Center of Burlington Cty.	242	6	2.48	1	0.41	1	0.41
Monmouth Medical Center	78	2	2.56	0	0.00	0	0.00
Morristown Memmorial Hospital	737	4	0.54	2	0.27	2	0.27
Newark Beth Israel Medical Center	46	0	0.00	0	0.00	0	0.00
Our Lady of Lourdes Medical Center	135	2	1.48	0	0.00	0	0.00
Overlook Hospital	9	0	0.00	0	0.00	0	0.00
Pascack Valley Hospital	45	1	2.22	0	0.00	0	0.00
RWJ University Hospital	158	2	1.27	0	0.00	0	0.00
Shore Memorial Hospital	12	0	0.00	0	0.00	0	0.00
Somerset Medical Center	49	3	6.12	0	0.00	0	0.00
South Jersey Hospital-Elmer	2	0	0.00	0	0.00	0	0.00
South Jersey Hospital-Bridgeton	295	2	0.68	0	0.00	0	0.00
St. Barnabas Medical Center	242	3	1.24	0	0.00	0	0.00
St. Clare's Hospital-Denville	11	1	9.09	0	0.00	0	0.00
St. Joseph's Wayne Hospital	3	0	0.00	0	0.00	0	0.00
St. Mary Hospital (Hoboken)	31	0	0.00	0	0.00	0	0.00
St. Mary's Hospital (Passaic)	5	0	0.00	0	0.00	0	0.00
St. Peter's University Hospital	433	7	1.62	0	0.00	0	0.00
Trinitas Hospital	21	0	0.00	0	0.00	0	0.00
UMDNJ-University Hospital	82	1	1.22	0	0.00	0	0.00
Underwood-Memorial Hospital	59	3	5.08	1	1.69	1	1.69
Union Hospital	25	0	0.00	0	0.00	0	0.00
University Medical Center at Princeton	126	3	2.38	1	0.79	1	0.79
Valley Hospital	90	0	0.00	0	0.00	0	0.00
Virtua-Memorial Hospital Burlington Cty.	88	4	4.55	0	0.00	0	0.00
William B. Kessler Memorial Hospital	22	0	0.00	0	0.00	0	0.00
Total	**4,448**	**56**	**1.26**	**6**	**0.13**	**7**	**0.16**

APPENDIX

TABLE 3. DEMOGRAPHIC CHARACTERISTICS OF BARIATRIC SURGERY PATIENTS BY SEVERITY OF ILLNESS: 2003

Age Group	SEVERITY OF ILLNESS (APR-DRG)				Total	% of high/very high
	Low	Moderate	High	Very High		
15-19	54.2	45.8	0.0	0.0	48	0.0
20-24	66.0	30.6	3.5	0.0	144	2.0
25-29	65.5	31.6	2.0	0.9	348	4.1
30-34	62.5	35.0	1.4	1.1	555	5.7
35-39	58.5	37.8	2.9	0.8	733	11.0
40-44	55.6	40.2	3.6	0.6	691	11.8
45-49	51.0	44.5	3.5	1.0	683	12.7
50-54	49.7	42.5	6.5	1.3	600	19.2
55-59	46.1	44.1	7.7	2.0	401	15.9
60-64	38.0	47.4	11.1	3.5	171	10.2
65-69	30.2	41.3	25.4	3.2	63	7.3
70+	36.4	63.6	0.0	0.0	11	0.0
Total	**54.6**	**39.9**	**4.4**	**1.1**	**4,448**	**100.0**
Sex						
Female	58.4	37.2	3.6	0.8	3,514	63.3
Male	40.1	50.2	7.4	2.2	934	36.7
Total	**54.6**	**39.9**	**4.4**	**1.1**	**4,448**	**100.0**
Payer						
Medicare	32.4	49.1	14.6	3.9	281	21.2
Medicaid ***	37.5	62.5	0.0	0.0	16	0.0
Private	56.2	39.1	3.7	0.9	3910	73.9
Self Pay	50.0	43.8	4.7	1.6	64	1.6
Other	56.5	39.0	3.4	1.1	177	3.3
Total	**54.6**	**39.9**	**4.4**	**1.1**	**4,448**	**100.0**
Deaths	0.0	0.0	0.0	100.0	**6**	

Source: New Jersey 2003 UB Data.

* Percent of row total

** Shows the column distribution of high and very high severity within a demographic characteristic of a patient

*** UB data does not distinguish Medicaid HMOs from other HMOs. However, the Division of Medical Assistance and Health Services reports that there were 114 gastric bypass surgeries for Medicaid clients covered by Medicaid HMOs. The demographic data for these cases is likely included in the private insurance category in this table.

APPENDIX

TABLE 4. DEMOGRAPHIC CHARACTERISTICS OF BARIATRIC SURGERY PATIENTS BY RISK OF MORTALITY: 2003

Age Group	RISK OF MORTALITY (APR-DRG)					Deaths
	Low	Moderate	High	Very High	Total	
15-19	100.0	0.0	0.0	0.0	48	.
20-24	97.2	2.8	0.0	0.0	144	.
25-29	96.6	2.9	0.3	0.3	348	.
30-34	96.9	2.0	0.5	0.5	555	1
35-39	96.3	2.6	0.8	0.3	733	.
40-44	95.7	3.6	0.4	0.3	691	.
45-49	94.4	4.1	1.0	0.4	683	1
50-54	91.3	7.0	0.8	0.8	600	1
55-59	90.5	7.2	1.7	0.5	401	2
60-64	83.0	12.9	2.3	1.8	171	1
65-69	69.8	15.9	7.9	6.3	63	.
70+	63.6	36.4	0.0	0.0	11	.
Total	**93.9**	**4.6**	**0.9**	**0.6**	**4,448**	**6**
Sex						
Female	95.0	3.8	0.9	0.3	3,514	4
Male	89.9	7.4	1.2	1.5	934	2
Total	**93.9**	**4.6**	**0.9**	**0.6**	**4,448**	**6**
Payer						
Medicare	79.7	13.2	4.3	2.8	281	2
Medicaid ***	81.3	18.8	0.0	0.0	16	.
Private	95.0	3.9	0.7	0.4	3,910	4
Self Pay	92.2	6.3	1.6	0.0	64	.
Other	94.9	4.0	0.6	0.6	177	.
Total	**93.9**	**4.6**	**0.9**	**0.6**	**4,448**	**6**
Deaths	0.0	0.0	0.0	100.0	**6**	

Source: New Jersey 2003 UB Data.

* Percent of row total

** Deaths are those during the initial admission.

*** UB data does not distinguish Medicaid HMOs from other HMOs. However, the Division of Medical Assistance and Health Services reports that there were 114 gastric bypass surgeries for Medicaid clients covered by Medicaid HMOs. The demographic data for these cases is likely included in the private insurance category in this table.

APPENDIX

TABLE 5. BARIATRIC SURGERIES BY SEVERITY OF ILLNESS, 2003

HOSPITAL	SEVERITY OF ILLNESS (APR-DRG)*				Total	Column %
	Low	Moderate	High	Very High		
Atlantic City Medical Center-City	44.7	47.6	4.9	2.9	103	2.3
Barnert Hospital	10.4	75.5	13.2	0.9	106	2.4
Bayonne Medical Center	80.0	0.0	20.0	0.0	5	0.1
Cathedral-St. Michael's Medical Center	42.9	51.4	0.0	2.9	35	0.8
Chilton Memorial Hospital	56.1	43.9	0.0	0.0	41	0.9
Englewood Hospital and Medical Center	59.8	25.8	10.3	4.1	97	2.2
Hackensack University Medical Center	69.5	28.3	1.6	0.6	817	18.4
Holy Name Hospital	50.7	44.0	2.2	3.0	134	3.0
Jersey Shore University Medical Center	58.2	30.9	9.1	1.8	55	1.2
Kennedy Memorial Hospitals UMC-Stratford	33.3	55.6	11.1	0.0	9	0.2
Lourdes Medical Center of Burlington Cty.	43.0	50.8	5.4	0.8	242	5.4
Monmouth Medical Center	56.4	41.0	1.3	1.3	78	1.8
Morristown Memmorial Hospital	62.1	34.1	2.6	1.2	737	16.6
Newark Beth Israel Medical Center	28.3	60.9	8.7	2.2	46	1.0
Our Lady of Lourdes Medical Center	25.2	68.1	5.9	0.7	135	3.0
Overlook Hospital	55.6	44.4	0.0	0.0	9	0.2
Pascack Valley Hospital	82.2	13.3	0.0	4.4	45	1.0
RWJ University Hospital	69.0	27.8	3.2	0.0	158	3.6
Shore Memorial Hospital	58.3	41.7	0.0	0.0	12	0.3
Somerset Medical Center	69.4	30.6	0.0	0.0	49	1.1
South Jersey Hospital-Elmer	47.8	46.4	5.4	0.3	295	6.6
South Jersey Hospital-Bridgeton	0.0	50.0	50.0	0.0	2	0.0
St. Barnabas Medical Center	72.7	25.6	0.8	0.8	242	5.4
St. Clare's Hospital-Denville	45.5	54.5	0.0	0.0	11	0.2
St. Joseph's Wayne Hospital	0.0	100.0	0.0	0.0	3	0.1
St. Mary Hospital (Hoboken)	77.4	22.6	0.0	0.0	31	0.7
St. Mary's Hospital (Passaic)	20.0	80.0	0.0	0.0	5	0.1
St. Peter's University Hospital	48.3	46.9	4.2	0.7	433	9.7
Trinitas Hospital	71.4	28.6	0.0	0.0	21	0.5
UMDNJ-University Hospital	59.8	36.6	1.2	2.4	82	1.8
Underwood-Memorial Hospital	45.8	39.0	11.9	3.4	59	1.3
Union Hospital	40.0	52.0	8.0	0.0	25	0.6
University Medical Center at Princeton	47.6	30.2	19.8	2.4	126	2.8
Valley Hospital	25.6	64.4	10.0	0.0	90	2.0
Virtua-Memorial Hospital Burlington Cty.	14.8	77.3	6.8	1.1	88	2.0
William B. Kessler Memorial Hospital	4.5	63.6	27.3	4.5	22	0.5
Total	**54.6**	**39.9**	**4.4**	**1.1**	**4,448**	**100.0**

Source: New Jersey 2003 UB Data.

* Percent of row total

APPENDIX

TABLE 6. BARIATRIC SURGERIES BY RISK OF MORTALITY, 2003

HOSPITAL	RISK OF MORTALITY (APR-DRG)*				Total	Deaths**
	Low	Moderate	High	Very High		
Atlantic City Medical Center-City	92.2	3.9	3.9	0.0	103	.
Barnert Hospital	86.8	11.3	1.9	0.0	106	.
Bayonne Medical Center	80.0	20.0	0.0	0.0	5	.
Cathedral-St. Michael's Medical Center	91.4	2.9	2.9	0.0	35	.
Chilton Memorial Hospital	97.6	2.4	0.0	0.0	41	.
Englewood Hospital and Medical Center	84.5	11.3	2.1	2.1	97	.
Hackensack University Medical Center	96.9	2.3	0.2	0.5	817	
Holy Name Hospital	94.0	2.2	3.0	0.7	134	1
Jersey Shore University Medical Center	90.9	7.3	0.0	1.8	55	.
Kennedy Memorial Hospitals UMC-Stratford	88.9	11.1	0.0	0.0	9	.
Lourdes Medical Center of Burlington Cty.	94.6	4.1	0.0	1.2	242	1
Monmouth Medical Center	97.4	1.3	1.3	0.0	78	.
Morristown Memmorial Hospital	95.8	2.8	0.9	0.4	737	2
Newark Beth Israel Medical Center	82.6	10.9	4.3	2.2	46	.
Our Lady of Lourdes Medical Center	94.8	3.7	1.5	0.0	135	.
Overlook Hospital	100.0	0.0	0.0	0.0	9	.
Pascack Valley Hospital	95.6	2.2	2.2	0.0	45	.
RWJ University Hospital	96.2	3.2	0.0	0.6	158	.
Shore Memorial Hospital	100.0	0.0	0.0	0.0	12	.
Somerset Medical Center	95.9	4.1	0.0	0.0	49	.
South Jersey Hospital-Elmer	94.6	5.4	0.0	0.0	295	.
South Jersey Hospital-Bridgeton	100.0	0.0	0.0	0.0	2	.
St. Barnabas Medical Center	96.7	2.5	0.0	0.8	242	.
St. Clare's Hospital-Denville	100.0	0.0	0.0	0.0	11	.
St. Joseph's Wayne Hospital	100.0	0.0	0.0	0.0	3	.
St. Mary Hospital (Hoboken)	100.0	0.0	0.0	0.0	31	.
St. Mary's Hospital (Passaic)	80.0	20.0	0.0	0.0	5	.
St. Peter's University Hospital	94.9	3.9	0.9	0.2	433	.
Trinitas Hospital	100.0	0.0	0.0	0.0	21	.
UMDNJ-University Hospital	96.3	2.4	1.2	0.0	82	.
Underwood-Memorial Hospital	81.4	10.2	5.1	3.4	59	1
Union Hospital	92.0	8.0	0.0	0.0	25	.
University Medical Center at Princeton	77.8	18.3	2.4	1.6	126	1
Valley Hospital	88.9	10.0	1.1	0.0	90	.
Virtua-Memorial Hospital Burlington Cty.	90.9	6.8	1.1	1.1	88	.
William B. Kessler Memorial Hospital	54.5	40.9	0.0	4.5	22	.
Total	**93.9**	**4.6**	**0.9**	**0.6**	**4,448**	**6**

Source: New Jersey 2003 UB Data.

* Percent of row total

** Deaths are those during the initial admission.

APPENDIX

TABLE 7. DISTRIBUTION OF HOSPITAL STAY (IN DAYS), 2003*

HOSPITAL	Total Number of Hospitalization Days										Total Hospital Stay Days	Total Number of Patients**	Average Number of Hospital Stay Days
	<=2	3-4	5-9	10-14	15-19	20-24	25-29	30-49	50-79	80-138			
Atlantic City Medical Center-City	82	14	5	2	2						299	105	2.8
Barnert Hospital	18	63	22	2	1			1			453	107	4.2
Bayonne Medical Center		2	3								29	5	5.8
Cathedral-St. Michael's Medical Center	1	19	10	3	1			1			224	35	6.4
Chilton Memorial Hospital	37	4									78	41	1.9
Englewood Hospital and Medical Center	5	63	19	4	1	1	1	2		1	770	97	7.9
Hackensack University Medical Center	229	535	40	5	6	4		1			2594	820	3.2
Holy Name Hospital	51	62	16	2	3			1		1	587	136	4.3
Jersey Shore University Medical Center		39	13	2	1			1		1	390	57	6.8
Kennedy Memorial Hospitals UMC-Wash. Twp.	4	2	2		1						44	9	4.9
Lourdes Medical Center of Burlington Cty.	2	196	35	3	2	1	1	1		1	1111	242	4.6
Monmouth Medical Center	38	32	7	1	1						222	79	2.8
Morristown Memmorial Hospital	608	91	25	3	3	4		3		2	2229	739	3.0
Newark Beth Israel Medical Center		7	34	1	1	1	1		1		369	46	8.0
Our Lady of Lourdes Medical Center		124	9	3							467	136	3.4
Overlook Hospital	7	1	1								24	9	2.7
Pascack Valley Hospital	15	22	5	1			1	1			203	45	4.5
RWJ University Hospital	97	43	15	1	1			1	1		502	159	3.2
Shore Memorial Hospital		2	9	1							70	12	5.8
Somerset Medical Center	41	4	3		1						129	49	2.6
South Jersey Hospital-Bridgeton	1	197	94	2				1	1		1357	296	4.6
South Jersey Hospital-Elmer		1	1								10	2	5.0
St. Barnabas Medical Center	76	155	10		1			1			727	243	3.0
St. Clare's Hospital-Denville	1	7	1		1			1			85	11	7.7
St. Joseph's Wayne Hospital		1	1	1							19	3	6.3
St. Mary Hospital (Hoboken)	13	18									82	31	2.6
St. Mary's Hospital (Passaic)		1	4								31	5	6.2
St. Peter's University Hospital	221	140	55	9	4	3			1		1540	433	3.6
Trinitas Hospital	5	12	3	1							81	21	3.9
UMDNJ-University Hospital	25	53	5								247	83	3.0
Underwood-Memorial Hospital	3	35	14		3	1	1	2			378	59	6.4
Union Hospital	13	11	1								68	25	2.7
University Medical Center at Princeton	46	62	11	4			1	1	1		522	126	4.1
Valley Hospital		41	48							1	536	90	6.0
Virtua-Memorial Hospital Burlington Cty.		62	18	4	2	1	1				442	88	5.0
William B. Kessler Memorial Hospital	2	14	5		1						95	22	4.3
Total	1,641	2,135	544	55	37	16	7	19	5	7	17,014	4,466	3.8

Source: New Jersey 2003 and 2004 UB Data.

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

APPENDIX

TABLE 8. 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

APPENDIX

TABLE 8. DIAGNOSTIC CODES CONSIDERED TO BE DIRECTLY RELATED BARIATRIC SURGERY COMPLICATIONS

Diagnosis Codes	Description
56081	Intestinal or peritoneal adhesions with obstruction
56089	Other intestinal obstruction
5643	Vomiting following GI surgery
56489	Disorders of intestine
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 2003 UB Data