Ethical Issues Associated with Bariatric (Weight Loss) Surgery

January 14, 2004

Customer for the Ethics Advisory Group
The customer for the January 14 meeting was Dr. Bill Corwin, Medical Director for Utilization Management and Clinical Policy.

Background
The United States is experiencing an epidemic of obesity. Under the widely used classification developed by the National Institutes of Health, 34% of the adult population is “overweight” (BMI 25 – 29.9) and another 27% meet criteria for “obesity” (BMI ≥ 30). The overall prevalence of obesity has increased more than 75% since 1980. Obesity is associated with increased type II diabetes, cardiovascular disease (especially hypertension), osteoarthritis and multiple other conditions. An obesity-related process called “Syndrome X” or “metabolic syndrome” that includes insulin resistance, abdominal obesity, hypertension, diabetes and lipid abnormalities has recently been described. (see http://www.americanheart.org/presenter.jhtml?identifier=4756)

Epidemiologists anticipate that obesity may soon exceed smoking as a source of impaired health and shortened life span. (Yanovski SZ, Yanovski JA. Obesity. New England Journal of Medicine 346:591-602, 2/21/02)

In 1991 the National Institutes of Health developed a consensus statement on “Gastrointestinal Surgery for Severe Obesity” that is widely used as guidance for clinical practice. The Consensus Panel recommended that:

1. Patients seeking therapy for severe obesity for the first time should generally be encouraged to try non-surgical treatment approaches including dietary counseling, exercise, behavior modification and support.
2. Gastric surgery should be generally be limited to a) patients with “clinically severe obesity” (BMI ≥ 40) or for those with a BMI of ≥ 35 with significant medical comorbidities who b) have not been able to lose weight through medical approaches and c) have no untreated medical cause for obesity such as adrenal or thyroid disease.
3. Surgery should only be recommended to a) well informed and motivated patients b) after careful evaluation by a multidisciplinary team with medical, surgical, psychiatric and nutritional expertise.
4. Surgery should be performed by surgeons with substantial experience in settings with adequate support for all aspects of management and assessment.
5. Surgery should be followed by lifelong medical followup.

1 The NIH defines obesity in terms of the BODY MASS INDEX (BMI), which can be calculated by multiplying weight in pounds by 703, dividing the result by height in inches squared. Normal weight is defined as BMI = 18.5 to 24.9. Overweight = BMI 25 to 29.9. Obesity is divided into Class 1 (BMI = 30 – 34.9), Class 2 (BMI = 35 – 39.9) and Class 3 or “Clinically Severe Obesity” (BMI greater than 40).
In December 2001, ten years after the original NIH consensus statement, the National Institute of Diabetes and Digestive and Kidney Diseases issued a publication on bariatric surgery that showed the degree to which the surgical approach had become mainstream:

Severe obesity is a chronic condition that is difficult to treat through diet and exercise alone. Gastrointestinal surgery is the best option for people who are severely obese and cannot lose weight by traditional means or who suffer from serious obesity-related health problems.

The pool of potential candidates for bariatric surgery is large. In 2000 4.7% of the population had clinically severe obesity (BMI ≥ 40) (Flegal KM, Carroll MD, Ogden CL, Johnson CL. Prevalence and Trends in Obesity among US Adults, 1999-2000. JAMA 288:1723-1727, 10/9/02.) The frequency of surgery is increasing rapidly, from 47,000 in 2001 to 63,000 in 2002 to approximately 100,000 in 2003. HPHC’s experience has followed the national trend, with a greater than 100% increase from 2001 to 2003.

Until recently the two most commonly used surgical procedures have been Vertical Banded Gastroplasty and Roux-en-Y Gastric Bypass, but these are now being supplanted by the Laparoscopic Adjustable Gastric Banding (LAGB) procedure:

a) In **Vertical Banded Gastroplasty** the stomach is partitioned into a small pouch by use of staples. A band is placed at the lower end of the pouch to create a sphincter into the remainder of the stomach. The band causes food to be retained in the small pouch for a longer period of time. This creates a feeling of fullness and leaves no room for further food intake until the pouch empties.

b) The **Roux-en-Y Gastric Bypass** procedure also involves creating a small stomach pouch, but it also adds an element of reduced absorption of nutrients by bypassing the first segment of the small intestine (duodenum) and attaching the stomach pouch to the second segment of the small intestine. The process of bypass reduces the amount of calories the body absorbs from food, but it also reduces the intake of important nutrients. (see http://www.roux-n-y.com/WhatIs.html for an especially clear explanation of this procedure)

c.) In the **Laparoscopic Adjustable Gastric Banding procedure**, a small pouch is created in the upper part of the stomach by wrapping a band around the stomach to leave only a narrow passage from the newly created pouch and the larger, lower portion of the stomach. Its effect is to reduce how much you can eat at a single meal. The procedure is done with a laparoscope, thus avoiding a large incision and the complications a large incision can cause. Some types of gastric bands are connected by a tube to a reservoir that is placed under the skin of the upper abdomen. In a doctor's office, small amounts of saline solution can be injected into the reservoir or removed to enlarge or shrink the band around the stomach. (If you are interested in seeing how much of a
commercial enterprise Bariatric Surgery has become, do a Google search for “laparoscopic adjustable gastric band” and check out the sponsored links. For a clear diagram of LABG see: http://www.csmc.edu/2443.html

After surgery most patients lose weight quickly and continue to lose for 18 to 24 months. Most regain 5 to 10 percent of the weight they lost, but many maintain a substantial long-term weight loss, often more than 100 pounds. Weight loss is often correlated with significant improvement in diabetes, blood pressure and other weight related medical conditions.

Bariatric surgery, however, has risks. Mortality from the surgery itself is less than 1%, but post-surgical leakage into the abdomen or malfunction of the outlet from the stomach pouch can require further surgery. Vitamin deficiencies, gallstones and osteoporosis are among the other complications that can occur. With LABG, the stomach can slip under the band, causing the pouch to distend and empty poorly; scar tissue can build up around the band and reduce the outlet; the band can loosen and fail to restrict eating; and, in rare cases, the band can penetrate the stomach.

With regard to the basic objective of weight reduction the surgery is not foolproof – some patients ultimately regain the weight they lost, through varying combinations of enlargement of the stomach pouch and return to compulsive patterns of eating.

**Questions for the Ethics Advisory Group**

Bariatric surgery is a textbook example of an area of health care calling for evidence based management of utilization and ethically guided deliberation about coverage policies. At one extreme bariatric surgery can be seen as a life saving, medically necessary intervention that potentially reverses the inevitable trend to sometimes fatal medical conditions. At the other extreme it can be seen as a technical fix for a subjectively distressing result of choices with regard to eating and exercise. The surgery has risks and represents a significant cost (approximately $15-20K). In the past year alone the number of patients at HPHC that are having Bariatric Surgery doubled. The public, however, has voted with its feet against having insurance companies take an active role in managing utilization. **The EAG was asked to recommend a framework of values that HPHC could use in its oversight of bariatric surgery.**

If a team of medical anthropologists came from Mars to study US practices with regard to weight, they would find our culture distinctly confusing. On one hand they would observe multiple components of the US culture that appear designed to fatten us up – farm subsidies, the fast food industry, all manner of devices to reduce physical exercise, and ubiquitous monitors (television and computer) that keep us sitting still, often with snacks at our side. On the other hand they would observe massive expenditures for diet regimens and weight loss drugs, widespread anorexia, stigmatizing attitudes towards the obese and burgeoning bariatric surgery. **In a culture that is deeply conflicted in its approaches to weight and obesity, how can HPHC best pursue its mission of “improving the health of the people we serve and the health of society”?**
Relevant precedents
On May 28, 1998 the EAG discussed “Making Life Better is our Life’s Work – at what cost? The Ethics of Resource Allocation and the Case of Viagra.” The EAG criticized the commonly used term “life style drug” which public policy discussions were applying to Viagra. The EAG distinguished between the potential value of Viagra in improving what it regarded as a basic component of human well-being – sexual function – and the legitimate question of how HPHC should manage the cost implications of the recently FDA approved medication. It saw the use of a derisive term like “life style drug” as an effort (not occurring at HPHC) to substitute disparagement and stigma for open and honest setting of limits. In its subsequent policy making about Viagra HPHC acknowledged the benefits that Viagra offers and explained that its decision to limit coverage to four pills per month was made on the basis of responsible cost management.

Obesity treatment is sometimes trivialized as “tummy tucks.” The 1998 EAG precedent emphasizes the values of a) combating that kind of stigmatizing language and b) a high degree of openness about the rationales for coverage policies.

On November 15, 2001 the EAG discussed “The Ethics of Last Chance Therapies: Liver Transplantation for HIV-Positive Patients.” The core question involved what kinds of standards to apply in circumstances of clinical need but unproven medical outcomes. The EAG endorsed a strongly evidence-based perspective, and was critical of what it saw as a US “tendency to assume that new treatments and technologies are inevitably superior to old ones as placing too much credulity in medical miracles and too little emphasis on potential harms.” The EAG “supported using a high standard of evidence in making coverage policy,” and emphasized that “the key issue is for all stakeholders…to understand the rationale for the standards that a program uses and the trade offs involved in choosing a standard.” As different as the 2001 case was from the topics that were discussed on January 14, 2004, the precedent encourages a strongly evidence based approach to managing coverage policies and an open, educative style of communication about policy rationales.

EAG DISCUSSION/RECOMMENDATIONS
Bill Corwin opened the meeting by describing bariatric surgery from the perspective of a health plan medical director with responsibility for utilization management. Patient interest in the surgery is high and increasing. More and more surgeons and hospitals are offering the surgery. Although overall mortality from the surgery is less than 1% the public has become alarmed about well-publicized recent deaths. Those who pay for health care – governments, employers, and the health plans they contract with – are acutely concerned about rising costs.

Bill Corwin explained that insurance coverage for bariatric surgery is determined by application of “medical necessity criteria.” Some self-insured employers have chosen to manage utilization by altogether excluding coverage for bariatric surgery, and some national insurance programs also exclude it. HPHC has used the National Institute of Health criteria (see pages 1-2 above) to determine coverage. Bill invited the EAG to comment on these criteria from the perspective of values.
With regard to medical necessity criteria, Jim Sabin reported that he has been in contact with the Appeals Section in the Health Plan Division of the Michigan Office of Financial and Insurance Services. Under Michigan’s “Patient Right to Independent Review Act” one of the areas of greatest controversy has been coverage for bariatric surgery. The state has been concerned that insurers are setting the bar for coverage of bariatric surgery too high. Michigan's independent review cases are posted (without names) on a public website, and the April 25, 2003 entry (http://www.michigan.gov/cis/0,1607,7-154-10555_20594_20596-82522--,00.html) shows that Priority Health, a Michigan insurer, was then using medical necessity criteria of a) a BMI of > 40 and “one acutely life-threatening comorbidity…or two life-threatening comorbidities, one of which is poorly controlled diabetes on standard therapy” or b) a BMI of > 55 “with one or more serious co morbidities directly related to obesity.” In the April 25, 2003 case Michigan concluded that Priority Health’s criteria were too stringent and overturned Priority’s denial of coverage.

The EAG’s overall perspective was that bariatric surgery has an important contribution to make in the management of obesity. There was no sentiment that the service should not be offered, that the NIH criteria were too lax (or too stringent), or that the criteria for determining medical necessity should be set much higher as Priority Health had done in Michigan. Several participants reported vignettes about friends who have had the surgery and benefited greatly from it.

The EAG encouraged HPHC to think about bariatric surgery not just at the point of referral for surgery but in the context of promoting quality improvement for the full spectrum of obesity services, earlier in the patient’s course before the question of surgery arises, and in the post surgical phase as well. The group’s broad value perspective led to recommending a disease management/health promotion approach to obesity treatment. When members become candidates for bariatric surgery the health system should track their course backwards. What was their earlier trajectory? Are there presurgical interventions that could have been applied that might have reduced the suffering and medical morbidity the member has experienced and possibly obviated the need for surgery? Are members adequately informed and educated so that they can be active partners in deciding about whether to proceed with surgery and planning for successful post surgical management?

Several participants in the meeting noted an element of vagueness in the NIH criteria. The criteria state that patients should initially “be encouraged to try non-surgical treatment approaches…” and that surgery “should generally be limited to patients…who have not been able to lose weight through medical approaches…” These participants expressed concern about whether patients were reliably receiving high quality education, guidance and support re non-surgical approaches prior to considering surgery, and noted that patients deemed “[unable] to lose weight through medical approaches” could range from those who tried diligently for years to others who had only made brief, poorly supported, half-hearted efforts. One participant in the discussion electrified the group by describing a personal experience of losing at least as much weight as could be hoped for
from successful bariatric surgery through a self-guided program involving multiple supports.

Participants cited HPHC’s outreach programs to members with conditions like diabetes and asthma as examples of the kind of program that could ideally be available to patients who might ultimately be candidates for bariatric surgery. [The outreach programs were discussed at the EAG meetings of 5/16/02 (“Becoming an eHealthPlan: The ethics of ‘high touch/high tech’”) and 1/16/03 (“Targeted Outreach: The Ethics of “Data Mining”).] One participant asked if the HPHC database would allow a predictive modeling approach prior to the question of bariatric surgery arising. These suggestions embodied the perspective that an insurer could potentially add value by supporting the network in taking a long-term disease management approach to members with obesity.

The EAG expressed concern that as bariatric surgery is more widely disseminated it will be more difficult for patients and payers to be confident about the quality of the services being provided. A web search under “bariatric surgery” brings up advertisements from multiple regional, national and international programs that are competing for referrals. Bariatric surgery is clearly a moneymaker for hospitals and surgeons. Participants suggested that a “Center of Excellence” strategy that encouraged members to seek services at sites that provide excellent presurgical, operative and post surgical services could promote the values of quality care, a disease management perspective on obesity, furthering research in the area, and – possibly – favorable financial outcomes.

HPHC staff explained some of the complexities health insurers face in dealing with obesity services. It is easier for insurance to cover services that can be specified explicitly and that are like other things health insurance traditionally covers. The procedures associated with bariatric surgery can be specified in this explicit manner, and other surgical services are routinely covered by health insurance. Conversely, health insurers tend to not cover services which are difficult to specify, especially if they are not the kind of services that are typically covered. The perverse impact of these insurance practices is that health insurance tends not to cover non-medical weight management programs, but does cover the byproduct of severe failure of weight management if the result of that failure requires surgery.

In this context Vin Capozzi told the EAG that there are insurance models emerging across the country that try to emphasize prevention rather than waiting until a condition requires major interventions like bariatric surgery. One such example is the “HealthCredits” program developed by PacifiCare, a California-based company. (Information about the HealthCredits program can be found at http://www.pacificare.com, selecting the “About PacifiCare” option, the “Newsroom” option, and then scrolling to the press release of 11/6/03.) The concept in insurance models of this kind involves developing incentives to support health maintenance activities such as weight management.

Throughout the discussion the EAG emphasized that obesity is a national epidemic and that bariatric surgery should be thought about in a broad public health and societal
context. Health plans have a distinctive role to play on behalf of the employers and public agencies that pay for health care, but a comprehensive approach involving prevention and health promotion as well as treatment requires a series of partnerships. Ralph Fuccillo reported that the HPHC Foundation is developing an initiative in the area of reducing childhood obesity, and that the Center for Child Health Care Studies in the Department of Ambulatory Care and Prevention is conducting research in the area. With regard to quality standards for bariatric surgery, malpractice liability insurers and other entities focused on patient safety are natural partners.

Summary

1. With regard to Bill Corwin’s request for a framework of values for HPHC’s oversight of bariatric surgery, the EAG made three recommendations that amplified components of the National Institute of Health Criteria:
   a) Seek cost effective opportunities to support “upstream” services aimed at shifting the trajectory of obesity earlier in the clinical course with the objective of reducing suffering and medical morbidity and possibly obviating the need for surgery itself. (Building on NIH recommendations # 1 and # 2b)
   b) Encourage optimal education so that members can make well-informed decisions about surgery with full understanding of and commitment to the lifelong post surgical requirements. (Building on NIH recommendations # 3a and # 5)
   c) Consider strategies such as identifying Centers of Excellence to ensure that members are evaluated and treated in programs with high levels of surgical experience, broad multidisciplinary strengths and a commitment to making the best possible use of non-surgical interventions. (Building on NIH criteria # 3b and # 4)

2. The EAG felt that bariatric surgery can offer significant benefits to correctly selected and supported recipients. It did not favor the kind of efforts to control utilization by setting extremely high medical necessity criteria that were described by the Michigan external review program. (described above on page 5)

3. Obesity is a national epidemic. Bariatric surgery is one piece of a comprehensive approach. The EAG encouraged HPHC to take a broad public health perspective on obesity and to partner with other programs and organizations in an effort to alter the course of the national trend.

4. The EAG thanked Bill Corwin for giving it an opportunity to engage with this important area of medical and public health policy!

Jim Sabin