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WHITE PAPER

ASGE EndoVators Summit: Defining the role and value of endoscopic therapies in obesity management

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On November 20 and 21, 2016, the American Society for Gastrointestinal Endoscopy (ASGE) and the Association for Bariatric Endoscopy (ABE) hosted the EndoVators Summit at the Institute for Training and Technology in Downers Grove, Illinois to define the role and value of endoscopic therapies in obesity management. Nearly 100 obesity management experts, innovators, and key decision makers from industry, insurers, and regulatory agencies gathered to review the current state of the obesity epidemic in America and the role that endoscopic bariatric and metabolic therapies (EBMTs) could play in the management of this chronic disease. Additionally, ASGE invited leaders of societies with an interest in EBMTs to participate in an exchange of ideas related to the training, research, and education in EBMTs with the goal of identifying areas of cooperation and coordination. The following societies were represented:

American Society for Gastrointestinal Endoscopy
The Association for Bariatric Endoscopy
American Society for Metabolic and Bariatric Surgery
International Federation for the Surgery of Obesity and Metabolic Disorders
The Obesity Society
American Association for the Study of Liver Diseases
American Society of Transplantation
American College of Gastroenterology
Academy of Nutrition and Dietetics
North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition
Society of American Gastrointestinal and Endoscopic Surgeons

The Summit program was organized into 4 general sessions, with each session comprising 3 to 5 lectures from domain experts. The sessions were:

1. Overview of the obesity problem: epidemiology, etiology, and impact on public health
2. How should we treat obesity? Components of a successful program
3. Endoscopic treatment of obesity
4. The nuts and bolts of reimbursement

This white paper summarizes the individual lectures for each session and outlines actionable items or areas of consensus reached by society leadership pertinent to that session.

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SESSION 1: OVERVIEW OF THE OBESITY PROBLEM: EPIDEMIOLOGY, ETIOLOGY, AND IMPACT ON PUBLIC HEALTH

Lecture: The epidemic—implications for public health and the healthcare system (William Dietz, MD)

Obesity is a chronic relapsing disease with staggering prevalence worldwide. In the United States, over 37% of the adult population is obese.[1] After decades of growth, there have been some signs of stabilization in the obesity epidemic, which may be attributable to preventive efforts. However, the prevalence of severe obesity (body mass index [BMI] >40) continues to grow (10% in women, 6% in men).[2] Additionally, about 50% of obesity in adults began when they were aged between 20 and 39 years,[3] which may represent an important target for preventive efforts because of a halo effect (the phenomenon of an individual's weight loss efforts positively influencing the weight loss efforts of family and friends). There are substantial ethnic differences in the distribution of obesity. Lower socioeconomic status has a clear impact on rates of obesity in white women but not in other groups.[4] Obesity has been linked to over 260 medical comorbidities, including cardiovascular disease, diabetes, and cancer.[5] Medical costs associated with obesity have been climbing. In 2008, the total cost of obesity was approximately $147 billion.[6] Rising costs are due mainly to the increasing frequency of multiple comorbidities among adults with obesity.[7]

Primary prevention is key. Education is paramount. Treatment needs to focus on widespread, scalable strategies. Specific efforts should focus on combating the bias and stigma of obesity that exist in the public, among patients, and even among healthcare providers. Other areas of focus include reducing energy intake (sugary drinks, high-energy dense foods), increasing daily physical activity and decreasing television time, pregnancy care (focusing on before-pregnancy weight, weight gain during pregnancy, diabetes, and smoking), breastfeeding, and sleep. Adverse childhood experiences[8] contribute to chronic diseases like obesity and may predict responses to treatment and relapses.[9,10]

Lecture: Weighing the importance of genetics, metabolism, environment, and psychology (Christos Mantzoros, MD)

Certainly there are genetic contributions to obesity. However, with the exception of certain rare monogenic causes of obesity,[11] the vast majority of obesity cases have polygenic contributors.[12] A current research focus is epigenetics—the concept of stably heritable phenotypes that result from chromosomal changes without alterations in the DNA sequence.

Environmental factors important in the pathogenesis of obesity include increase in portion sizes,[13] increasing energy intake from selected food items, increased sugar consumption,[14] television watching,[15] and sedentary lifestyle.[16]

There is a significant biological underpinning to obesity. Adipose tissue is an endocrine organ that secretes leptin to the brain, altering energy expenditure and food intake.[17] Hormones (insulin, leptin, ghrelin, peptide YY, glucagon-like peptide-1) secreted by the stomach, colon, adipose tissue, and small intestine affect the hypothalamus, reward centers in the brain, and higher centers in the central nervous system.[18]

New medications target the hormones identified to play a role in the pathogenesis of obesity (eg, liraglutide, a glucagon-like peptide-1 analogue).[19] Research in enhanced medication delivery may improve compliance, such as orally absorbable peptides or weekly and/or monthly depot injections. Likewise, new endoscopic therapies for obesity that alter anatomy or place barriers to absorption also alter hormonal mechanisms. Bariatric surgery also beneficially alters hormone levels, which may contribute to decreased body weight.

Lecture: The impact of socioeconomic status and race and/or ethnicity on obesity in the United States (Dean Schillinger, MD)

Vulnerable populations are population subgroups that are exposed to a greater "risk of risks" because of social, economic, political, structural, and historical forces, and they thereby are at a disadvantage with respect to their health and healthcare. People who did not graduate from high school have a higher average BMI than college graduates, and similarly, the populations with the lowest income have a higher average BMI than those with the highest income. With regard to interactions between income and sex, one of the common myths is that all or virtually all low-income people are far more likely to be obese. In reality, research studies demonstrate that an increased risk of obesity is more consistent for female adults and children of low-income or low socioeconomic status than for men and boys. However, the interactional relationships among race and/or ethnicity, sex, income level, and obesity are more complex. For example, obesity prevalence is similar among men across income levels, but it is higher among non-Hispanic black and Mexican American men of higher income. Additionally, lower-income women have a higher prevalence of obesity, and the overall trend is similar across race and/or ethnicity but is not significant in Hispanic white women. Therefore, it is not accurate to say that virtually all low-income people are more likely to be obese. Obesity disproportionately impacts patients who have public insurance or are without insurance compared with those with private insurance.

There are a host of mechanisms that link social vulnerability to obesity, including government policies, food insecurity, health literacy, sugar-sweetened beverages, and effects that occur at a neighborhood level.

The 1973 farm bill and food subsidies. One quarter of appropriated funds goes to federal subsidies that finance the production of corn, soybeans, wheat, rice, dairy, and livestock (via subsidies on grains). More than half of all calories consumed by American adults during 2001 to 2006 originated from subsidized food commodities. A large proportion of these foodstuffs are converted into high-fat meat and dairy products, refined grains, high-calorie drinks, and processed foods. Three quarters of appropriated funds go to the Supplemental Nutrition Assistance Program, previously known as *food stamps*, which are disproportionately used to purchase these subsidized, less-expensive, calorie-dense foods.[20]

Food insecurity. *Food insecurity* refers to the limited or uncertain availability of nutritionally adequate and safe foods or the limited ability to acquire acceptable foods in socially acceptable ways. Food insecurity affects 14% of U.S. adults and 35% to 40% of U.S. families at or below the poverty level. Food insecurity is linked to obesity because it leads to food overconsumption during times of food availability and/or adequacy in order to compensate for times in which food is unavailable or inadequate. Food insecurity leads to consumption of less-expensive, calorie-dense foods at the expense of more costly fresh fruits and vegetables.[21-22]

Liquid sugar intake. Liquid sugar intake through consumption of inexpensive sodas and fruit juices contributes to obesity because of its high calorie content and possibly by increasing lipogenesis.[23]

Limited health literacy. One third of the American adult population suffers from limited health literacy. Health illiteracy is more common among minority and low-income subgroups, and it is the strongest predictor of increased consumption of sugar-sweetened beverages.[24]

Home neighborhood. The neighborhood in which one lives also strongly impacts the risk of obesity. Those who live in economically deprived neighborhoods have higher BMIs, even after adjusting for individual socioeconomic status. Possible mechanisms include decreased exercise because of lack of walkable streets and increased violence, limited access to grocery stores and healthy foods, and peer and/or social networks that model unhealthy diets and lifestyles.

Society leadership summit: the obesity pandemic

Society leadership underscored obesity as a chronic, relapsing disease with a complex web of environmental and biological etiologies. Associated with over 200 comorbidities, obesity is a healthcare crisis. An effective strategy for combating this crisis must be predicated on public health education, preventive efforts, and development and/or implementation of scalable treatments. Within medical specialty societies, there exist pockets of interest in obesity research and treatment that must be identified and linked in a collaborative effort to speak with a more powerful, unified voice. Society leadership expressed enthusiasm in promoting intersociety dialogue, finding a commonality of goals, and uniting efforts to further obesity research through public and professional education. Given the predominance of lower socioeconomic status as a strong risk factor for obesity and given the fact that a majority of obese individuals in the United States are of lower socioeconomic status, new endoscopic and related innovative therapies must be accessible to those who are publicly insured (eg, Medicaid populations) and of low income. In order to ensure the greatest population benefit to such new therapies, it is vital that reimbursement policies ensure that those who have the greatest need for these therapies are not left behind.

SESSION 2: HOW SHOULD WE TREAT OBESITY?

Lecture: Medical therapies: exercise, nutrition, and medications (Robert Kushner, MD)

Obesity is a patient-centered condition. Before seeking medical consultation, patients often consult self-help books and Internet and/or commercial weight-loss programs and try over-the-counter medications and dietary supplements.[25] Both patients and providers need to recognize obesity as a chronic relapsing disease.[26-27] As such, there needs to be a push by patients and providers alike to seek and provide care and counseling much earlier in the disease course. The U.S. Preventive Services Task Force recommends screening for and management of obesity in adults (B recommendation)[28] as well as behavioral counseling for obesity (B recommendation).[29] Multiple society guidelines provide a framework for learning about and treating obesity (American Association of Clinical Endocrinologists/American College of Endocrinology obesity guidelines 2016,[30] metabolic surgery guidelines 2016,[31] American College of Cardiology/American Heart Association/The Obesity Society obesity guidelines 2014[32] ENDO Pharma Management 2015).[33]

The current medical model for obesity management (BMI >25) includes[34] (1) lifestyle modification (physical activity, diet, and behavioral changes) as a foundational treatment, (2) anti-obesity medications (BMI >27 with comorbidities or BMI >30), and (3) obesity surgery (BMI >35 with comorbidities or BMI >40).[1]

To be successful, any treatment for obesity (including medications, EBMTs, and surgery) should be built upon a firm foundation of lifestyle modifications. Five medications are U.S. Food and Drug Administration (FDA)–approved for obesity:[35] orlistat, lorcaserin (Belviq), phentermine/topiramate ER (Qsymia), naltrexone/bupropion SR (Contrave), and liraglutide (Saxenda). The rationale for medications is to help patients adhere to a lower-calorie diet more consistently to achieve sufficient weight loss and health improvements in combination with increased physical

activity.[32] Medications may or may not be covered by insurance. Studies of medications for obesity have generally demonstrated weight loss of 5% to 12% of initial weight.[36]

Importance of behavior modification (Bonnie Spring, PhD)

Behavior modification provides patients with the tools to promote self-regulation, stress management, and habit modification to fight back against a toxic food environment. Behavior modification supports positive changes in diet and exercise through self-monitoring. Extensive contact with an interventionist familiar with weight management is crucial (at least 14 times over a 6-month period for initiation and at least monthly for maintenance).[37] Intensive behavioral weight management interventions have demonstrated strong efficacy for weight-loss initiation but a more modest impact on maintenance of weight loss.[38,39] Self-monitoring of adherence to dietary intake restrictions is one of the most important behavioral factors for weight-loss initiation. It appears that increased moderate vigorous physical activity is required for successful weight-loss maintenance. The need for multiple sessions represents a major barrier for behavioral modification, although remote interventionist contact seems to be effective (Power trial). Newer technologies that include mobile apps for real-time decision support, self-monitoring, and remote coaching may expand the reach of behavioral interventions. Although technology is evolving rapidly, the underlying principles to promote behavioral modification remain unchanged. It is hoped that new research will lead to more efficient delivery of behavioral interventions and promote the adoption of a stepped-care algorithm when behavioral interventions are ineffective.

Non-surgical management of obesity and diabetes (Osama Hamdy, MD)

Type 2 diabetes is closely linked to obesity. Approximately 80% to 85% of patients with Type 2 diabetes are obese. It is now recognized that a comprehensive lifestyle intervention program that is designed to promote long-term weight loss, like the Why WAIT program (Weight Achievement and Intensive Treatment) at the Joslin Diabetes Center, not only prevents or improves Type 2 diabetes but may reverse it.[40] Proper lifestyle-management programs can achieve long-term weight loss in many patients with diabetes without the need for surgery. The important components of such a program include structured nutrition therapy, an adequate variety of physical activity that maintains lean muscle mass, cognitive behavioral support, and group intervention and education. It also includes adjustment of diabetes medications to enhance weight reduction and prevent weight regain. Most recent data showed that the Why WAIT program results in maintenance of weight loss of 6.4% at 5 years with significant improvement in many cardiovascular risk factors.[41] Well-designed lifestyle-management programs can be a cost-effective intervention for the prevention and treatment of diabetes, as it reduces total healthcare costs by 27% and diabetes-related costs by 44% per year.

Bariatric surgery: Optimal patients, preferred options, and outcomes (Bipan Chand, MD)

Bariatric surgery has been shown, in multiple studies, to lead to significant and durable weight loss.[42] Currently, it is indicated for patients with a BMI >35 who have comorbidities or patients with a BMI >40. The most commonly performed bariatric surgeries worldwide are vertical sleeve gastrectomy and Roux-en-Y gastric bypass. The adjustable gastric band and biliopancreatic diversion are less frequently performed in the United States.[43] The laparoscopic approach for these surgeries now is considered the standard of care. Sleeve gastrectomy, the most commonly performed bariatric surgery, results in as much as 70% excess weight loss (EWL) at weight nadir and long-term weight loss of 50% EWL.[44] Vertical sleeve gastrectomy produces effective and sustained weight loss that is comparable with that seen after Roux-en-Y gastric bypass. The morbidity and mortality of bariatric surgery have improved significantly, with 30-day mortality rates of 0.1% for vertical sleeve gastrectomy and 0.15% for Roux-en-Y gastric bypass.[45] Rates of adverse events now approximate those of gallbladder surgery, and nutritional deficiencies can be corrected with proper monitoring. Not withstanding its demonstrated efficacy and relative safety, only 1% to 2% of the eligible population with obesity undergo bariatric surgery.

More recently, the goal of bariatric surgery has shifted from a primary focus on weight loss to improvement of metabolic comorbidities. In obese diabetics, bariatric surgery has been shown to be superior to intensive medical therapy for improving glycemic control, reducing cardiovascular risk, and reducing utilization of pharmacotherapy.[46] Because of its demonstrated efficacy, revised indications for bariatric surgery soon may include the treatment of patients who have Type II diabetes with Class 1 obesity (BMI 30-34.9)—or for Asian diabetics, an even lower BMI threshold.[47] Gastric banding, sleeve gastrectomy, and gastric bypass have been shown in randomized, controlled trials to be safe and effective treatment for patients with BMIs of 30 to 35 in the short and medium term.[48,49]

How to establish a collaborative program (Shelby Sullivan, MD)

The optimal multidisciplinary weight-management program should include an endoscopist who is experienced in bariatric treatments (who may be the bariatric surgeon, depending on expertise), a bariatric surgeon, an endocrinologist and/or obesity medicine physician, a registered dietitian, an exercise specialist, a behavior coach, a psychologist, and a nurse or physician extender. A variety of practitioners can perform behavior coaching provided

that they have training in behavior coaching for weight loss.

Collaboration among different obesity management specialists is crucial for optimal patient care in obesity, including initial weight loss and weight loss maintenance. The collaboration between the proceduralist and obesity medicine and/or endocrinologist is important for helping with weight-loss maintenance and for informed decisions regarding the escalation of care. Likewise, the collaboration between the surgeon and endoscopist is important and useful for the management of adverse events and the escalation to endoscopic or surgical therapy. Every team member is important for providing adjunctive lifestyle therapy. Obesity care should be optimized within a collaborative program. Specialists in obesity management may consider joining a pre-existing multidisciplinary group or building a virtual center with referrals to other obesity treatment practitioners.

Society leadership summit: current treatment of obesity

Society leadership recognized that there is a pervasive prejudice among the general population and healthcare providers alike that obesity is a lifestyle choice instead of a disease—a prejudice that erects barriers to care access. Moreover, there are insufficient numbers of providers trained in the care of patients with obesity to match the scale of the problem. Therefore, collaboration among obesity care specialists is vital.

Society leadership endorsed the idea of uniting advocacy efforts to educate and guide primary care physicians in the proper screening, management, and/or referral of patients with obesity. Additionally, screening for and management of obesity should be recognized as a quality metric. Society leadership agreed that lifestyle modification provides essential treatment for obesity and is the critical foundation of any surgical or endoscopic bariatric therapy.

SESSION 3: ENDOSCOPIC TREATMENT OF OBESITY

Lecture: Review of FDA-approved devices (Steven Edmundowicz, MD)

There are currently 4 FDA-approved devices for primary endoscopic treatment of obesity. They include 3 intragastric balloons and an aspiration device. An endoscopic suturing device with FDA approval for the general indication of tissue apposition in the GI tract is being used for endoscopic sleeve gastroplasty. At present, none are covered by major insurers and, therefore, require patient self-payment.

Orbera balloon (Apollo EndoSurgery, Austin, Tex, USA). This is a saline solution–filled balloon (400-700 mL) that is implanted for up to 6 months and requires endoscopic placement and removal. This device met 2011 Preservation and Incorporation of Valuable Endoscopic Innovations criteria for efficacy and safety as a primary endoscopic treatment and for bridge treatment.[50] By these criteria, for a primary obesity intervention in Class II/III obese individuals, a device should achieve at least a mean 25% EWL at 12 months. Additionally, there should be a significant difference of at least 15% EWL between the intervention and control groups. Furthermore, the absolute minimum weight-loss threshold for any non-primary EBMT (eg, bridging) should be 5% of total body weight. Finally, the incidence of serious adverse events should be $\leq$5%.[51,52]

The ReShape Integrated Dual Balloon System (Reshape Medical, Inc, San Clemente, Calif, USA). This has a dual-balloon design (750-900 mL). The balloons are saline solution–filled and require endoscopic placement and removal. Efficacy was demonstrated in a randomized sham-controlled trial.[53]

Obalon balloon (Obalon Therapeutics, Inc, San Diego, Calif, USA). This system is composed of 3 separate balloons that are swallowed and filled to 250 mL with a nitrogen-mix gas. Endoscopic removal is required. Efficacy was demonstrated in a randomized sham-controlled trial.[54]

Aspire Assist (Aspire Bariatrics, Inc, King of Prussia, Penn, USA). This is a PEG-like device that allows aspiration of 25% to 30% of calories ingested. A randomized controlled trial showed 31% EWL at 52 weeks.[55] Adverse events are similar to those of PEG devices. Patients with an eating disorder were excluded from this trial. The Assist device has a counter that restricts the total number of aspirations that can be performed in a specified period. This device may contribute to a change in eating behavior, namely, increased chewing (to facilitate aspiration) and lowered total calorie consumption.

The Apollo OverStitch device (Apollo EndoSurgery, Inc, Austin, Tex, USA). This device is used to create an endoscopic sleeve gastroplasty. A multicenter study of 242 patients reported 15% total body weight loss at 6 months. This was not a randomized controlled trial, and only 22.2% of patients had weight recorded at 12 months, limiting the evaluation of durability.[56]

Lecture: Consideration of other gastric devices (Richard Rothstein, MD)

Multiple endoscopic devices and procedures targeting the stomach (beyond balloons) are in development but not yet approved for clinical use.

Baronova Transpyloric Shuttle (BAROnova, Inc, San Carlos, Calif, USA). This device is designed to intermittently obstruct the pylorus. It is endoscopically placed and removed. The original device resulted in frequent ulcers and was therefore redesigned. The U.S. End Obesity Trial is a randomized sham-controlled trial that just completed enrollment.

Spatz balloon (Spatz FGIA, Inc, Great Neck, NY, USA). This is a saline solution–filled, adjustable balloon that is currently under investigation in an FDA-approved trial. Endoscopy is used for placement, adjustment, and removal.

Allurion balloon (Allurion Technologies, Natick, Mass, USA). This saline solution–filled balloon is swallowed and therefore does not require endoscopic placement. After 4 months, it spontaneously deflates and passes. It is currently under investigation in a European trial.

Magnetically actuated capsule gas-filled balloon. In conjunction with a balloon that can be swallowed, an external magnet triggers an internal magnetic switch to combine acetic acid and bicarbonate that produces and inflates the balloon.

Gelesis (Gelesis, Inc, Boston, Mass, USA). This is an ingestible hydrogel that swells on contact with water. There are 2 types: Gelesis 100 for weight loss and Gelesis 200 for Type 2 diabetes. Gelesis is currently under investigation in an FDA pivotal trial.

Endoscopic sewing devices (Apollo EndoSurgery, Austin, Tex, USA). Several sewing devices are available or under investigation. The Apollo OverStitch is commercially available in multiple countries (including the United States), and another device (USGI Medical, San Clemente, Calif, USA) is available in Europe and the Middle East. In the United States, the USGI Pose procedure recently completed its FDA trial.[57]

Full Sense device (BFKW, Grand Rapids, Mich, USA). This is a modified gastroesophageal stent designed to provide expansion of the gastric cardia, which may induce a sense of satiety. It is currently under investigation in a European study.

Botox A injection (Allergan plc, Dublin, Ireland). The practice of Botox injection into the stomach is currently being studied in select centers. Available evidence shows equivocal efficacy.

Lecture: Review of small-bowel devices (Christopher Thompson, MD)

Bariatric surgery results in beneficial metabolic outcomes, and surgeries that involve more extensive small-bowel manipulation achieve greater effects on glucose control.[58,59] These lessons from surgery have led to the development of small-bowel devices intended to treat diabetes through GI hormonal changes (incretin effect).[60]

Endobarrier (GI Dynamics, Boston, Mass, USA). This device is a duodenal-jejunal liner that has shown significant improvement in glycemic control in 5 multicenter, randomized, controlled trials. However, the U.S. pivotal trial was stopped by the company because of an increased rate of serious adverse events. The company is engaged in discussions with the FDA to design a new trial.[61,62]

ReVita duodenal mucosal resurfacing procedure (Fractyl, Lexington, Mass, USA). This device produces hydrothermal ablation of the duodenal mucosa. In clinical trials, 6-month reductions in glycemic indices were demonstrated. Additionally, modest weight effects have been shown.[63] The device is under investigation in European trials.

GI Windows device (GI Windows, Inc, West Bridgewater, Mass, USA). This is an incisionless magnetic anastomosis system that creates a partial jejunal-ileal diversion. A 10-patient pilot study demonstrated glycemic improvement and 40% EWL at 12 months.[64] The device is under investigation in a European trial, and a South American trial is planned.

Other small-bowel devices. These include flow-altering devices and duodeno-jejunal liners (ValenTx device, ValenTx, Maple Grove, Minn, USA).

Lecture: Current reimbursement issues for bariatric procedures (Barham Abu Dayyeh, MD, MPH)

As previously noted, obesity is a chronic disease that is associated with numerous comorbidities. The evidence is clear that the magnitude of weight loss is strongly correlated with improvement in related comorbidities. The odds of clinically significant improvements in comorbidities are much greater when total body weight loss exceeds 10%.[65] Endoscopic therapies can achieve >10% total body weight loss in the majority of patients, with excellent safety and lower cost compared with bariatric surgery. Furthermore, they are anatomy preserving, reversible, and repeatable; thus, they are well-positioned to fill the gap in the management of obesity.[51] For maintenance of weight loss (a more difficult problem than initial weight loss), EBMTs can complement lifestyle, behavioral modifications, and pharmacotherapy.[66]

Currently, there are 2 paths to reimbursement for primary and revision endoscopic procedures: insurance and cash payment. Despite their demonstrated benefit for initial and long-term obesity management, EBMTs will remain an underused procedure until reimbursement is provided from government and private insurers. At present, the process for obtaining insurance coverage is long and uncertain. It commonly involves precertification justification and approval and postprocedure billing submission that uses the current procedural terminology (CPT) code 43999. Cash payment may be for the EBMT procedure alone or part of a large bundled payment for services including the preprocedure evaluation (endocrine, psychology, dietetics, and GI), the EBMT procedure, and multidisciplinary aftercare for 12 months. To recover the costs of the EBMT procedure, the following components need to be considered in the bundled payment: facility fees, anesthesia-provider fees, professional fees, device costs, and coverage of any medical adverse events.

Lecture: How applications and social media will aid in management (Shawn Garber, MD)

"Telehealth" is the use of electronic information and telecommunication technologies to support long-distance clinical healthcare. Mobile health is the use of mobile and wireless devices for healthcare services. Telehealth and mobile health may be most useful for maintaining weight loss through comprehensive aftercare programs

designed to increase patient compliance with lifestyle changes and diet. These virtual platforms may provide scalable and ongoing lifestyle modification reinforcement that is required to optimize both bariatric surgery and endoscopic procedures. Because of rising insurance costs (including deductible and co-pays) as well as opportunity costs (time away from work, travel, parking), a majority of patients prefer follow-up care through virtual visits rather than face-to-face visits. Moreover, telehealth and mobile health aftercare programs may be more cost effective for physicians. Examples of mobile healthcare programs for nutrition and fitness include Virtual Health Partners (New York, NY, USA), My Fitness Pal (San Francisco, Calif, USA), and Retrofit (Chicago, Ill, USA).

Society leadership summit: EBMTs

Society leadership shares optimism regarding the continued growth of EBMTs as a means of addressing the treatment gap (BMI 30-40) that separates medications and/or lifestyle therapy and surgery. Most FDA-approved EBMTs have demonstrated short-term safety and efficacy and, therefore, merit consideration for clinical use. EBMTs may play several therapeutic roles, including alternatives to primary therapy, bridge therapy, metabolic therapy, and early intervention or preemptive therapy. Each indication may have different thresholds for efficacy, risk profile, durability, and repeatability. It is anticipated that EBMTs in development and/or EBMTs used in combination (device/device or medicine/device) will exhibit higher efficacy. Ultimately, the value of EBMTs, defined as long-term efficacy and cost-effectiveness, must be demonstrated through appropriate studies and shared registries.

Optimizing patient outcomes with respect to EBMTs depends on proper training and measurement of quality outcomes. This issue was a central impetus in the formation of the ABE, which seeks to promote the safe and effective integration of EBMTs into practice. At a minimum, training modules should focus on requisite endoscopic skills (probably device-dependent), nutrition training, and a basic cognitive understanding of obesity medicine. It is anticipated that practitioners will have different skill sets, depending on their type of training (eg, gastroenterology vs general surgery) and level of training (residents/fellows vs practicing physicians). The goal should be to jointly devise a shared curriculum to sufficiently address gaps in knowledge and skill and to ensure uniformity of standards. Societies also should agree on requirements for hospital credentialing and privileging.

SESSION 4: THE NUTS AND BOLTS OF REIMBURSEMENT

Lecture: Running the gauntlet of regulatory approval for devices (Herbert Lerner, MD)

For devices that need regulatory approval from the FDA, there are several regulatory paths to market, based on the risk of the device and procedure—premarket Notification [510(k)-510(k) low-risk devices with substantial equivalence to currently approved "predicate devices"], de novo (low-risk to moderate-risk devices that have no approved "predicate" on the market), and a premarket approval application and/or Humanitarian Device Exemption, intended for novel technologies that generally require clinical data and need an investigational device exemption. There are several device classifications based on risk—Class 1 (lowest risk), Class 2 (moderate risk, usually require 510[k], only 10% to 15% require clinical data), Class 3—highest risk, require a premarket approval application or a Humanitarian Device Exemption. Most EBMTs will need a premarket approval application. The investigational device exemption allows an investigational device to be used in a clinical study to collect safety and effectiveness data.

The purpose of the investigational device exemption is to encourage discovery and development of useful medical devices for human use. There are various types of presubmission meetings regarding which sponsors should avail themselves. Sponsors should review FDA guidance documents and consult with the FDA early and often to finalize clinical study design, choice of endpoints, and sample-size calculations. Many delays in getting devices to market are related to failures in communication between the agency and sponsor. Most of these are avoidable with proper planning and good meetings. Device manufacturers are strongly encouraged to follow FDA advice on receiving its feedback. Given recent infection issues with duodenoscopes, the area of most concern to the FDA include biocompatibility and issues related to cleaning, disinfection, and sterilization.

Lecture: The process for pursuing Centers for Medicare and Medicaid Services payment (Glenn Littenberg, MD)

After FDA approval is obtained for a medical device, the traditional pathway to reimbursement requires the procedure to be given a CPT code. Once a CPT code is given, the Relative Value Scale Update Committee makes recommendations to the Centers for Medicare and Medicaid Services (CMS) regarding the relative value units to be assigned to the new CPT code. After its review, the CMS sets the final relative value units and payment for the CPT code. This process is slow, complex, and highly political, because representatives of societies that are not related to gastroenterology on the Committee generally are motivated to support lower relative value units. After this gauntlet is run, there is no assurance that adequate payment or coverage will be awarded. Hence, most, if not all, FDA-approved EBMTs are cash payment.

Compared with 10 to 20 years ago, there are higher hurdles to obtaining a CPT code and reimbursement: (1) the FDA has more stringent criteria for device approval; (2) the CPT technology assessment process has more

stringent evidence and literature requirements for approval of a Category 1 CPT code; (3) to guide deliberations on the fair relative value scale for a procedure, the Committee conducts a survey that requires a minimum of 30 valid responses from providers, for which 100 to 500 requests are sent; (4) increasingly, the CMS reviewers may disagree with the Committee on their recommendations, raising questions among societies and device manufacturers of the value of the Committee; (5) although the Relative Value Scale Update Committee and/or CPT process applies to government insurance only, private payers typically will not cover devices that are investigational or lack a CPT code; (6) an alternative to the current cash payment model for EBMTs may be found in a physician-focused alternative payment model. For example, the Medicare Access and CHIP Reauthorization Act of 2015 intends to transition medical care to financial risk bearing, clinically integrated systems (Quality Payment Program). Similarly, private payers are exploring intensive "medical homes," which use bundled payments for healthcare episodes as opposed to traditional fee-for-service. In this type of reimbursement model, certain predefined groups of patients with obesity may have coverage for medications, EBMTs, and surgeries. From these group outcomes, quality data and cost data are collected and compared with untreated cohorts, which help drive subsequent discussions to extend coverage and shared savings programs.

Lecture: Integrating the evidence and stakeholder perspectives: the California Technology Assessment Forum (Jeffrey Tice, MD)

The California Technology Assessment Forum (CTAF) is a nationally recognized community forum that reviews objective evidence reports of devices and drugs and develops recommendations for how stakeholders can apply this evidence to patient care. From the payers' perspective, devices, including diagnostics, are not held to the same evidence standard for FDA approval as drugs, and, therefore, insurers and other payers will rely on organizations like CTAF to perform another layer of systematic review of the literature regarding efficacy and, more recently, cost-effectiveness and budget-impact analyses.

CTAF's technology assessment criteria include (1) the technology must have final approval from the appropriate government regulatory bodies; (2) scientific evidence (preferably Level 1) must permit conclusions concerning the effectiveness of the technology regarding health outcomes that matter to patients (eg, heart attacks, not lower cholesterol); (3) the technology must improve net health outcomes; (4) the technology must be as beneficial as established alternatives; (5) clinical improvement must be attainable outside the investigational setting.

From the CTAF perspective, early FDA approval decreases the likelihood that good trials will be performed, and longer follow-up often is needed to evaluate harms.

Lecture: The insurer's perspective: What evidence and data are needed to merit payment? (Opella Ernest, MD)

EBMTs are considered experimental or investigational. Payers, like Health Care Services Corporation, invite experts' participation to help review new literature in their annual medical policy development cycle. Health Care Services Corporation uses the same assessment criteria as CTAF for review of new medical technologies.

Society leadership summit: reimbursement

Society leadership acknowledges that the traditional process to obtain FDA approval, a CPT code, and reimbursement for a new medical device is long, expensive, and unpredictable. Nonetheless, the continued growth and success of EBMTs and other promising technologies requires negotiating this process and, ultimately, obtaining coverage. Success will depend on collaboration among medical and surgical societies, industry, academia, and community providers to lobby payers with a unified voice. EBMT registries will be important to demonstrate long-term safety and improvement in clinically important comorbidities in order to show value to payers. Also, there may be an opportunity to provide coverage for EBMTs by partnering with CMS and private payers to establish intensive medical homes (obesity homes) that use episode-of-care bundled payments as opposed to a fee-for-service reimbursement strategy.

DISCUSSION

The overarching goal of the EndoVators Summit was to gather obesity management experts, innovators, leaders representing various medical and surgical subspecialty societies, and key decision makers from industry, insurers, and regulatory agencies to review the current state of the obesity epidemic in America and the role that EBMTs could play in the management of this chronic disease. Ultimately, the Summit served as a reminder that we are all committed to treating the same problem, albeit in different ways and at different levels. As such, we all need to promote more dialogue, search for commonality of goals, and unite advocacy efforts.

There was widespread acknowledgement that obesity, and its attendant 200+ comorbidities, is a full-fledged public health emergency, and its treatment desperately requires new approaches. First and foremost, obesity needs to be recognized fundamentally as a chronic relapsing disease and not a lifestyle choice, a stigma held by many patients and providers, which hinders access to care. Changing this perception will require public and professional education campaigns and possibly identifying quality metrics for primary care physicians and pediatricians that reward obesity screening and referral to specialists. Second, public health initiatives—such as mandating physical

TABLE 1. The path forward: joint cooperation

1. United efforts to lobby payers
2. Shared registry
3. Joint training curriculum
4. Education of PCPs to improve access to obesity care
5. Work together to solicit research funding
6. Work together to lobby Washington, DC

PCP, Primary care physicians.

education in schools, implementing taxes on sugar-sweetened drinks, and better food warning labels to increase health literacy—should be supported by all who are interested in obesity because they have the potential to stabilize and reverse disturbing epidemiologic trends. Third, lifestyle modifications provide the foundation for the prevention and treatment for obesity upon which the success of adjunctive treatments depends: medications, endoscopic therapies, and/or surgery. Fourth, a multidisciplinary approach yields the best results in the treatment of obesity, particularly in the maintenance phase.

The field of endoscopic bariatric therapies is nascent, but there is a shared optimism that EBMTs will represent a viable option in the armamentarium of obesity treatments. EBMTs may be applied at different points of intervention: alternative to primary therapy, bridge therapy, metabolic procedures, and early or preemptive intervention. Differences among them will impact their initial efficacy, the durability of weight loss, safety, and the need and/or possibility of repeat procedures. At the time of this writing, 5 EBMTs are FDA approved. We await long-term studies to establish their durability and impact on important comorbidities such as diabetes.

Currently, there are several hurdles to successful integration of EBMTs into clinical practice, which also represent potential areas of collaboration (Table 1). They include the following:

Training and credentialing. Training should focus both on technical skills (likely device-specific) as well as general knowledge of obesity medicine, nutrition, diet, and lifestyle management. A uniform training curriculum and credentialing process would be optimal to ensure minimum standards among physicians.

Research and registries. Collaboration on registries among GI and surgical endoscopists performing EBMTs would enhance capture of the requisite patient data needed by CMS and private payers to justify reimbursement. Current surgical registries are expensive, are not designed for the outpatient setting, and may require modification if used for EBMTs. Additionally, stakeholders should work together to solicit sufficient research funding from federal, industry, and foundation sources to develop studies with optimal design, sample size, and long-term follow-up.

Reimbursement. Currently, minimal insurance coverage means that most EBMTs will be performed on a cash-payment basis, limiting the number of patients who will benefit. Some practitioners have found success by approaching employer-based insurances, which have less health-plan turnover than other private insurers and have a greater incentive to support interventions that provide long-term health benefits and cost reductions. Long-term solutions also may be found in the establishment of obesity homes and bundled payments for episodes of care, which avoid the long, expensive, and uncertain pursuit of a CPT code. Research demonstrating cost savings of obesity treatments should be pursued.

Conclusion

Obesity is a public health crisis requiring a reexamination of current treatment paradigms. Debate pertaining to the management of this crisis must be reframed. Instead of seeing it as a consequence of bad lifestyle choices, we must recognize it as a chronic disease that arises from a complex web of environmental and biological factors and a primary driver of over 200 comorbidities. Reexamination of the obesity crisis also requires recognition of public education and preventive medicine as the keys to reversing its high prevalence in this country and around the world. Regardless of our specific interests or disciplines, all who are interested in reducing obesity and its devastating consequences must become public health advocates. Reexamination also means recognition that current treatment efforts are insufficient and fragmented. We must be open to new collaborations and scalable strategies to maximize the use of available resources and promote increased resources in the future. This means educating primary care physicians, encouraging the nascent field of EBMTs and virtual centers, promoting jointly devised obesity treatment curricula, and unifying multi-society efforts to lobby payers and garner research funding.

DISCLOSURES

Dr Ryou is the Founder of, has equity interest in, and is a consultant for GI Windows, Inc, and is a consultant for Medtronic/Covidien. Dr Thompson is a consultant for Boston Scientific, Medtronic, and GI Dynamics, is a consultant for and Advisory Board Member of USGI Medical and Fractyl, is a consultant for and has received research support from Olympus and Apollo Endosurgery, has received research support from Aspire Bariatrics and Spatz, and has an ownership interest in EndoTAGSS. Dr Edmundowicz discloses the following conflicts relevant to the Summit: SynerZ Medical, sleeve technology for obesity therapy, Scientific Advisory Board member 2013 to present, stockholder 2013 to present, consultant payments for labs and advisory meetings, purchased by Gore Medical in 2016 with all options exercised; Elira, device to stimulate T6 dermatome for obesity, medical advisory board member, stockholder and paid consultant 2015 to present; GI

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Abbreviations: ABE, Association for Bariatric Endoscopy; ASGE, American Society for Gastrointestinal Endoscopy; BMI, body mass index; CMS, Centers for Medicare and Medicaid Services; CPT, current procedural terminology; CTAF, California Technology Assessment Forum; EBMT, endoscopic bariatric and metabolic therapy; EWL, excess weight loss; FDA, U.S. Food and Drug Administration.

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