A Peer-Reviewed Publication

BARIATRIC TIMES

Clinical Developments and Metabolic Insights in Total Bariatric Patient Care

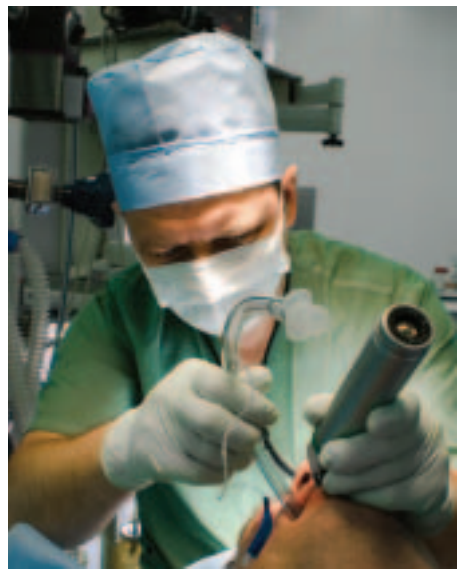
Volume 7, Number 4 April 2010

Inside

REVIEW

Awake Tracheal Intubation in Patients with Morbid Obesity:

When, Why, and How?



by JEREMY COLLINS, MB, ChB, FRCA, and JAY B. BRODSKY, MD

INTRODUCTION

Every anesthesiologist fears the situation of total inability to manage a patient's airway. When this occurs in a patient with morbid obesity (MO), the rapid development of severe hypoxemia exaggerates the critical nature of such an event. Recent data from the American Society of Anesthesiologists (ASA) Closed Claim Database justify this concern.[1] Patients with obesity were involved in 37 percent of all adverse airway events occurring during anesthetic induction, and in 58 percent of those events occurring following tracheal extubation. A large proportion of these situations resulted in either brain damage or death.

The *difficult airway* was defined by an ASA task force as the clinical situation in which a conventionally trained anesthesiologist experiences problems with face mask ventilation of the upper airway, tracheal intubation, or both.[2] They included a Difficult Airway Algorithm (DAA), a document that has become the foundation of airway management practice. The DAA provides a rational decision tree to follow when a difficult airway is either anticipated or arises unexpectedly. When difficulty is predicted, the algorithm may start with attempts at tracheal intubation before or after anesthetic induction.

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REVIEW

BARIATRIC SURGERY IN ADOLESCENTS

by NATAN ZUNDEL, MD, FACS; ELIAS CHOUSLEB, MD; and SONI CHOUSLEB, MD

INTRODUCTION

Obesity has become one of the most important chronic health problems in the world. It is estimated that it affects 20-25% of the adolescent population. Its impact on normal physical and psychological development is dramatic. (1,2) The epidemic increase of childhood obesity in the United States has resulted in significant obesity related co-morbid conditions, that previously where only seen in the adult population. (3) Currently the surgical treatment strategies for obesity in childhood and adolescence are still not well defined, and they may need to be somewhat different to those used in the adult population. Some also suggested that the criteria for indications for surgery should be different from the NIH recommendations for adults. But new, recent studies suggest that we can use the same NIH standards for the adolescent population. (4) Although surgery is not without risk, many healthcare professionals view it as an acceptable option. It is debatable if surgical treatment of childhood and adolescent obesity should be postponed until adulthood, when the individual has the legal authority to provide with informed consent and has full understanding of the possible

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COMMENTARY

The Battle for Access to Care for Treatment of Obesity

by ROBIN BLACKSTONE, MD, FACS, FASMBS

DEFINING THE BATTLE

"Obesity should be treated." This is the battle cry for our continuing effort to get fair access to care for the person whose life is affected by obesity. Body mass index (BMI) is a vital sign.

Surgeon General Richard Carmona, MD, cited obesity as the most important threat to national security due to cost of care, the related incidence of type 2 diabetes (T2D), and the number of people involved.

Our **[[[AUT: By our do you mean ASMBS?]]]** goal is that every American who has health insurance has a comprehensive benefit for the treatment of obesity. Will you become a warrior in this battle?

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The Battle for Access to Care for Treatment of Obesity

by ROBIN BLACKSTONE, MD, FACS, FASMBS

Bariatric Times. 2010;7(4):xx

ABSTRACT

This commentary piece is a call to action for all surgeons and integrated health team members to engage in active advocacy to achieve the American Society for Metabolic and Bariatric Surgery goal of a comprehensive benefit for the treatment of obesity. Included is a comprehensive review of the concept of obesity as a disease and the controversy involved in the argument that obesity is a matter of personal responsibility. This commentary discusses different sources of funding for bariatric surgery and the 2009 Mercer survey data on employer health coverage. It concludes with a summary of the current activities of the American Society for Metabolic and Bariatric Surgery and the Obesity Action Coalition in advocating for the patient with obesity and how you can get involved. A summary of the current draft of the American Society for Metabolic and Bariatric Surgery Access to Care statement is included. Will you become a warrior in the battle for access?

KEY WORDS: bariatric medicine; obesity; morbid obesity; weight loss; healthcare quality, access, and evaluation; cost-benefit analysis; delivery of healthcare; healthcare reform; health services accessibility; insurance benefits

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OBESITY IS A DISEASE

Recently, George Bray from the Pennington Biomedical Research Center (Baton Rouge, Louisiana) presented a comprehensive evaluation of the evidence for regarding obesity as a disease. In his comments, he cited the The Obesity Society's position statement, *Obesity 2008,* that in order for a condition to be declared a disease it had to meet the following criteria:

1) Impairment of normal functioning of some aspect of the body
2) Characteristic symptoms or signs
3) Resultant harm or morbidity to the entity affected.

In Bray's opinion, obesity meets all of these criteria. The chronic disease of obesity has an etiology (energy imbalance), pathology (large fat cells), pathophysiology (adipokines), clinical findings manifested as signs and symptoms (fatness and closely associated comorbid disease), treatment (diet, behavioral therapy, drugs, and surgery), and a prognosis (decreased fatness results in a change in prognosis). He compared it to hypertension, which is widely acknowledged as a disease. In 2009, Whitlock et al[1] demonstrated that as BMI increases there is a concomitant increase in mortality. Willett et al[2] demonstrated that even an increase in BMI within a "normal" range causes an increase in hypertension, cholesterol, T2D, and coronary heart disease. The optimal BMI appears to be just under 25kg/m^2. **[[[AUT: Please provide reference.]]]**

Currently, researchers are adding clarity to the biological and neurohormonal mechanisms by which the case for obesity as a derangement in control of metabolism, hunger, and satiety can be made. The case for obesity as a neurobiological disease follows other models (e.g., genetic predisposition manifested as disease in a particular environment and worsened by changes in control and regulation that occur with increasing levels of fatness), but it is complicated by the perception that obesity is a matter of personal responsibility.

If you are going to engage people in the discussion of access to care, this is one issue that you will have to understand and be able to discuss. It was a pivotal argument in the decision of a small county supervisor board not to continue the benefit for county employees in the state of Texas. The energy balance equation from which none of us can escape simply states that the amount of energy you take in is balanced against the amount of energy you burn. If you take in more than you burn, you gain weight.

This equation is true, but like many things in medicine it is impacted by the genetic inheritance of the patient, the environment into which he or she lives, and the impact of society on his or her choices. We do not want to foster a feeling that a patient affected by obesity is a victim; however, many are born with a predisposition to extract calories from the food they eat with poor or no regulation of their metabolism or signals for satiety and hunger. The literature demonstrates that these derangements worsen as the person gets bigger.**[[[AUT: Please provide reference/references.]]]** In addition, the patient must eat to sustain life, so abstention, which works in other diseases ike drug and alcohol addiction, is not possible in this disease. In fact, the person is impacted by the readily available calorie-dense foods. Obesity affects people in lower socioeconomic groups who have many personal responsibilities and few resources for help.**[[[AUT: Please provide reference.]]]** They may not be able to concentrate on their environment. The pressure in our society to be thin is based not on health, but on cosmesis. The emphasis on appearance contributes to the feeling of personal hopelessness that pervades this disease state. Once the person affected is 50 pounds or more over their ideal weight, they are not able to exercise consistently enough without injury to change the "energy out" part of the equation. These are not excuses for fatness, but the reality of the person interacting with his or her environment.

We need to create empathy and foster understanding for the person affected by obesity. People with obesity often suffer blatant discrimination and prejudice. Much of this callous treatment is the result of people perceiving that the individual with obesity has a choice to not be big and is not doing what it takes to change. This personal responsibility argument is pervasive and often expressed as unwillingness by people not affected by the disease to pay for treatment. Statements by leaders in major academic centers, like the statements made about the hiring of patients with obesity at the Cleveland Clinic, **[[[AUT: Are you referring to Cleveland Clinic Florida? Please provide reference.]]]** are further evidence that obesity is grouped with smoking rather than hypertension in people's minds and attitudes.

It is important to support efforts in preventing obesity. It is especially critical that we support efforts to decrease the level of obesity in children and adolescents. Children are developing adult comorbid diseases, like T2D, at an early age and obesity has a profound impact on their self-image. As we move to embrace the treatment of the chronic disease of obesity across the

continuum of the expression of the disease, we should support prevention and behavioral and medical treatment of obesity. In turn, we expect the support of our colleagues in acknowledging the highly effective and safe treatment of those most affected by morbid obesity and for the treatment of T2D with metabolic surgery. Surgery is only available to about one percent of the people affected by morbid obesity. **[[[AUT: Reference needed.]]]** It is not going to be the final answer to morbid obesity, but it must be the answer right now for those who are at risk to develop worsening physical health from their obesity.

DEFINING THE SOURCE OF PAYMENT FOR OBESITY TREATMENT

Patients. The most common source of payment for obesity treatment across the continuum of care is the personal money of the patient. Billions of dollars are spent out of pocket by patients for medications and behavioral therapy to achieve weight control. While some of these therapies have scientifically demonstrated value, many have not. There is little regulation of the "diet" industry and much of the advertising of products is tied to appearance issues associated with obesity rather than health-risk resolution. This has promoted one of the biggest myths in America, which is that weight is about your appearance and not about your health. Individual health plans do not offer a benefit for the treatment of obesity. Patients have been losing coverage for bariatric surgeries through their employers due to job loss or have been delaying the procedure indefinitely for fear of missing work.

Employers. It is best to think about employers in three groups:

Large companies with greater than 1,000 employees. These companies most often have self-funded health insurance benefits. They use various insurance companies to act as administrators of their own plans (i.e., third-party administrators). These employers select the benefits that they want to provide to their employees and operate outside of legislative mandates.

Companies with 50 to 999 employees. These companies may be self funded, but also rely more on the administrator to give them advice about their benefits. They may also purchase special riders to cover specific items like transplantation and bariatric surgery by purchasing these services through the insurance company's special network of excellence.

Small companies with less than 50 employees. In these companies, people have to buy third-party insurance. Outside of states with a legislative mandate (Indiana, New Hampshire, and Maryland) there is no "core" benefit included in the healthcare benefit that this size company can purchase. Virginia and Georgia require that a rider be offered, but they are prohibitively expensive. Many employers rely on healthcare consulting companies like Hewitt Associates (Lincolnshire, Illinois) or the information from organizations like the National Business Group on Health (NBGH) (Washington, DC) to get advice about what benefits it should offer.

There were wide expectations that benefits would become more limited with the economic downturn; however, the Mercer 2009 Survey data show the opposite (Table 1).

The Mercer 2009 United States National Survey of Employer-Sponsored Health Plans was designed by statisticians at Research Triangle Institute International, Research Triangle Park, North Carolina, and is now in its 24th year. The Mercer survey is the premier source of health benefit data for employers and the healthcare industry alike with more than 2,900 employers participating in 2009. Ethicon Endo-Surgery, Inc. (EES, Inc.), Cincinatti, Ohio, sponsors the bariatric surgery question in the survey.

Industry professionals who are following the obesity access-to-care story were queried as to what might account for this gain **[[[AUT: What gain?]]]**. Eric Cagun of the Advisory Board **[[[AUT: Advisory Board for what?]]]** cites the influx of high-quality data detailing the safety of the surgery and the positive return on investment (ROI) data. "The fact that employers aren't dropping bariatric surgery benefits in tough times may be a result of the increased clinical acceptance of bariatric surgery—people are finally recognizing the long-term clinical benefits that provide positive ROI for payers who cover the procedure," Cagun said. Henry Alder, director of reimbursement and healthcare economics, EES, Inc., said, "I believe much of the gains we are seeing are largely the result of the rapid response initiatives put in place a year ago with the American Society for Metabolic and Bariatric Surgery (ASMBS) access-to-care team, the Obesity Action Coalition (OAC), industry partners and, may I add, the EES healthcare policy managers and Johnson and Johnson's (J&J) state government affairs who are working very closely behind the scenes with our public and commercial employers."

TABLE 1. Data results from the Mercer 2009 United States National Survey of Employer-Sponsored Health Plans

MERCER DATA	COVERED WITH BEHAVIOR MODIFICATION	COVERED	NOT COVERED
2006	26%	24%	50%
2007	28%	18%	54%
2008	27%	24%	49%
2009	32%	23%	45%

Mercer 2009 U.S. National Survey of Employer-Sponsored Health Plans **[[[AUT: Please provide source of data.]]]**

TABLE 2. Judy Dean's translation: what we write and what the payer hears

PROFESSIONAL STATEMENT	INSURERS TRANSLATION
High-risk patient	Policy limitations on patient comorbidities
Unanswered questions	Investigational and no coverage
More results needed	Investigational and no coverage
Staged procedure	Policy limitations on who can get it

Health insurance companies. Health insurers often turn to guidelines and society position statements to help determine benefits. They usually convene an expert panel of surgeons once a year to give advice on determining benefits. Some are diligent about utilizing current data, others less so. While society position statements are meant to reflect an accurate summary of currently available data, they may not be as clear as they need to be in regard to gaining access. One example is the recent statement by the ASMBS on sleeve gastrectomy. Judy Dean, managing director of Judy Dean Consultants, LLC, offered a "translation" of what we write and what the payer hears (Table 2).

Health insurers that are still utilizing the out-of-date National Institute of Health (NIH) consensus guidelines of 1991 are far behind the data in our field. Using out-of-date information may further the strategy of the insurer to delay or deny coverage, which they perceive as being very expensive. Data on the investment of bariatric surgery, which demonstrates a two-year ROI, may be falling on deaf ears because the company may not believe they will have the business long enough to reap the reward of lower costs after surgery. The new NIH guidelines are being revised and should help clarify the role of surgical treatment of obesity for these companies. There is an opportunity to educate the medical directors of these health insurers by providing them with data on an ongoing basis. Getting access to the medical directors can be facilitated by the health policy managers working for our industry colleagues: Allergan, Inc., EES, Inc., and Covidien.

Government. Federal employees, military, and Medicare beneficiaries have a benefit. The Federal employees' health benefit plan is a model. In addition, 42 states offer a benefit for their employees. States without a benefit for state employees include Montana, Idaho, Utah, Kansas, Oklahoma, Texas, Louisiana, and South Carolina. Georgia and Mississippi added a benefit in 2009 and the same bill that was passed in Mississippi last year has been proposed in Louisiana. Both Texas (via legislation) and Kansas (via a health plan decision) are expected to add new benefits as of 2010. Some states like Pennsylvania include a benefit for state employees, but only under the most expensive preferred provider organization (PPO) plan. For determining which states have a covered benefit, we define coverage as having at least one plan available to state employees with a benefit or a known loophole. Arizona continued a benefit for its employees for 2009/2010 albeit with a 20-percent co-pay, and while the benefit for Medicaid patients was left in place, the state chose not to fund it. Forty-seven states offered coverage under Medicaid in 2009. Ohio, Mississippi, and Kansas do not offer coverage. Poor reimbursement of procedures often means very limited access and this poor utilization is becoming a challenge. Joe Nadglowski, OAC president and chief executive officer (CEO), said, "Poor utilization is often due to low reimbursements, but may be giving lawmakers and/or regulators the viewpoint that such coverage is unnecessary since procedures are rarely being performed on Medicaid patients in some states."

We are facing serious challenges in almost every state to maintain coverage in the face of the economic problems that each state is facing in their budget. Our strategy: In every single case, do not allow a benefit to get canceled or changed without pressure being brought to bear on the principals involved. To do this effectively we have to utilize all our resources.

Medicare. The National Coverage Decision (NCD) issued in February 2006 established coverage for Medicare recipients. In March 2009, an upgraded version of the NCD was issued. This has had wide impact encouraging other insurers/payers to add coverage although the effect has also had unintended consequences for patients as well when Centers for Medicare and Medicaid Services (CMS) limited the patients access to care to designated ASMBS Centers of Excellence or American College of Surgeons (ACS) Level 1 Centers. This has had the effect of decreasing the number of patients getting surgery as well as taking people out of their communities for procedures. Medicare volumes dropped after the 2006 NCD from 11,800 in 2005 (15 percent of the market) to 10,700 in 2006. Data suggest that Medicare represents 5 to 7 percent of the market or about 9,000 to 13,000 procedures a year. It is critical that Centers of Excellence participate in offering surgery to Medicare and Medicaid patients despite some of the issues involved with these federal and state programs, such as reimbursement at levels that do not cover the cost of the program, tertiary Medicare contractors that require six months medical weight-loss and other prohibitive requirements for reimbursement, and noncoverage of band fills, sleeve gastrectomy, and outpatient surgery.

In summary, despite the economic situation bariatric surgery volumes seem to be holding steady and in some cases flourishing. We are still very far from our goal of having a core benefit for obesity treatment. All parties who pay for treatment still fear being overwhelmed by cost of treatment and complications. They don't realize we only have the capacity to provide surgical treatment to only one percent of eligible patients.

HOW DO WE IMPROVE ACCESS?

The ASMBS organized the Access to Care committee in 2007. The committee decided in that year to support the pursuit of a comprehensive benefit for the treatment of obesity and to promote the society's overall strategic goals by aligning ourselves with our colleagues in behavioral and medical treatment. **[[[AUT: Sentence correct as edited?]]]** We have one core strategy that has proven to be critical to this battle for access: Never let one benefit change for the worse or be eliminated without an uproar!

Two initiatives were implemented in 2008 and 2009 by the ASMBS Access to Care committee: The ASMBS Access to Care Committee Rapid Response Team (RRT) and the State Access to Care Representative Program. The Rapid Response team (RRT) is a small group that includes the co-chairs of the committee, Drs. Robin Blackstone and John Morton; Georgeann Mallory, executive director of the ASMBS; Joe Nadglowski, president and CEO of the OAC; Chris Gallagher from Potomac Currents (National Lobbyist group) (Alexandria, Virginia); and representatives from our industry partners and the Surgical Review Corporation.

> Never let one benefit change for the worse or be eliminated without an uproar!

The goal of the RRT is to act as a clearinghouse for early warning of threats to benefits and coverage and the rapid mobilization of a coordinated response and to provide national expertise to state societies and local surgeons and patients. In 2008/2009, this included opportunities in Virginia and Texas and recently in Idaho. Many venues are local and affect specific programs or issues, but the RRT allows us to rapidly judge the threat, get the facts, and connect the people who may be able to make a difference.

Last year, each state society was asked to appoint a state advocacy resource (StAR) to the National Access to Care Committee. This individual acts as the conduit for State chapter members forwarding information to the national committee and coordinating access-to-care efforts in the state. The members of StAR went through media training last year and this year have been involved in a number of state and local skirmishes in the battle for access.

One very successful battle by Dr. Mitch Roslin, a StAR from New York, was in getting coverage of sleeve gastrectomy with United Health Care and Aetna. Dr. Roslin has strong personal relationships with key medical directors, a command of the literature, and a fire inon the state level and have a passion for this fight. **[[[AUT: Sentence unclear. Please revise.]]]**

One of the current hot issues facing payers and medical directors in the United States in the next few months is whether to cover sleeve gastrectomy in 2011. Dean Geraci, director, Healthcare Economics and Reimbursement for Covidien Surgical Devices, has been working hard to help educate surgeons who in turn educate the medical directors who can help get the sleeve included as an approved procedure. Sixty professionals from the Access to Care committee, a number of ad-hoc members, and members of the ASMBS Executive Council participated in a web conference in March 2010 to brief us on the situation with coverage of bariatric surgery in general and the sleeve in particular. The follow up to that call was a webinar where sophisticated training and discussion on the current data was made available, so that professional surgeon advocates could have the data available at their fingertips when speaking with medical directors, employers, and state and national legislators. The goal is to have the sleeve gastrectomy included in all benefits by the end of 2010. This is the kind of activity that shows how effective partnering can be.

ADVOCACY WORKS

The most important aspect of professional advocacy is that the individual is willing to step up to a position of leadership. There can be no doubt that advocacy works. In 2009, Senator Robert Clegg from New Hampshire sponsored and passed a bill mandating coverage of obesity in New Hampshire.

We know that a major part of getting in front of the people who can change the current situation is to have the support of patients. In 2005, we realized we were missing a key component in trying to achieve our access goal: we did not have a political voice. A senator from Colorado said "I can eliminate the benefit for bariatric surgery tomorrow and there would be not one patient on the steps of the Capitol."

The OAC, a nonprofit group organized in 2005, was formed to provide the political muscle that would allow us to do just that. The OAC currently has approximately 20,000 members, but a few new programs have been enacted to enable us to reach the goal of having 250,000 members by 2012. Individual surgeons have decided to give a membership to each patient undergoing surgery as part of their program of care, and Bariatric Advantage (Irvine, California) has tied a free membership to every patient who buys vitamins after surgery through their online website. With more than 200,000 patients a year having surgery, it will not take long to reach and exceed that goal. When the OAC becomes to obesity what Susan B. Komen is to breast cancer, those people in the legislature in a position to change the future for obese patients will hear the voices of our patients and those affected by obesity.

Currently, Gallagher of Potomac Currents is our eyes and ears in Washington, DC. This year Gallagher organized visits on the hill to key senators and representatives that have kept obesity on the forefront of the healthcare reform debate. Drs. John Baker, John Morton, and many others spent countless hours on the hill since the 2009 ASMBS meeting directly lobbying for the treatment of obesity in the future regulatory language of the bill. Our battle cry for Congress and State legislatures is that the new NIH guidelines on obesity treatment should be followed and comprehensive treatment should be available in any publically funded program.

DATA

One of the most important initiatives of our society in the last 10 years was to support the development of the ASMBS Center of Excellence Program. The organization of bariatric programs around safe practice was the heart of the movement to improve quality and safety by requiring every surgeon and program to enter their data in the national database, Bariatric Outcome Longitudal Database (BOLD) or if an ACS Center of Excellence, the ACS database program. These efforts were the natural extension of efforts by Mason and the founding fathers of the ASMBS to prove the value of their work by tracking their safety and outcomes data. The shift in practice to this type of reporting and the forthcoming pinnacle of clinical outcome management—risk-adjusted, outcome-based reporting for surgeons and programs—have established the ASMBS as a leader in quality for the entire practice of surgery. This marks a profound cultural shift in medicine by those of us who practice the art, acknowledging that the same measures of quality that govern the airline industry are applicable and desirable in surgery. As we all move forward trying to get comfortable with the new paradigm, which is costly and time consuming, we acknowledge that data are the answer to minimizing our critics and will open the doors to access. This

comprehensive reporting compliments the individual efforts being made to publish critical studies, such as the LABS consortium data in the *New England Journal of Medicine* **[[[AUT: Please provide reference.]]]** showing the relationship of individual patient risk and surgeon volume to outcomes and the article by Nguyen et al **[[[AUT: Please provide reference.]]]** of a five-year, randomized, prospective trial comparing the band and the bypass. To improve the ROI for surgery, we have to acknowledge and decrease our complications and improve the efficacy of the treatment options we deliver. We have to keep track of our individual results and report them with accuracy.

LEADERSHIP

At the end of the day, what you do as an individual matters. Here are the things you can do to improve access to care:

- Pursue excellence—it has no substitute.
- Enter your data. Data are the only answer to our critics.
- Support your bariatric surgery and bariatric medicine colleagues.
- Know the current literature.
- Make a commitment to educate the medical directors and legislators/senators in your state.
- Make a commitment to building patient members of the OAC.
- Advocate for the prevention of obesity and the treatment of those most affected by the disease.
- Advocate for the treatment of obesity across the continuum of care.
- Take care of the people in the emergency room. Read the new statement from the ASMBS on emergency department coverage in SOARD. **[[[AUT: Reference?]]]**
- Educate your colleagues about the need for access and the safety and efficacy of treatment of obesity.

THE ASMBS ACCESS TO CARE STATEMENT

Currently the Access to Care Committee and the Executive Council are working on a statement about access to be voted on by the membership in June 2010. This is a summary of our current thinking about this statement. Your input and comments are welcome.

- Obesity is a medical condition that meets all criteria currently established for treatment of a condition as a disease, including a genetic predisposition and personal and societal/environmental factors that contribute to expression of the disease.
- Obesity is an independent risk factor for heart disease and coexists in a high percentage of patients with hypertension, high cholesterol, and T2D.
- People who suffer from the disease of obesity should not be subjected to prejudice and discrimination in the access to treatment for the disease of obesity
- People who suffer from the chronic disease of obesity should have access to evidence-based medical, pharmaceutical, behavioral, and surgical care similar to the access provided for the evaluation and management of other chronic disease
- Prevention of obesity through new strategies of healthy lifestyles should not affect the commitment to treat those currently suffering from the metabolic consequences of the disease
- Surgical treatment of obesity and associated metabolic disease is effective and durable and decreases mortality
- All Americans should have a benefit for the comprehensive evidence-based treatment of obesity.
- Obesity should be treated.

To learn more about how you can help the OAC with our advocacy efforts, visit: http://www.obesityaction.org/multimedia/takingaction.php.

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FUNDING:
There was no funding for the development of this article.

FINANCIAL DISCLOSURES:
Dr. Blackstone has no financial disclosures relevant to the content of this article.

AUTHOR AFFILIATION:
Dr. Blackstone is Co-Chair, Access to Care Committee for the ASMBS.

[[[AUT: Please provide photo]]]

ADDRESS FOR CORRESPONDENCE:
Robin Blackstone, MD, FACS, FASMBS, 7421 E. Berridge Lane, Scottsdale, Arizona 86250; Phone: (602)-549-6790; Fax: (480)-348-1936; Email: blackstonemd@mac.com