AACE Position Statement

AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS' POSITION STATEMENT ON OBESITY AND OBESITY MEDICINE

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Abbreviations:

BMI = body mass index;

T2DM = type 2 diabetes mellitus

EXECUTIVE SUMMARY

A. The American Association of Clinical Endocrinologists (AACE) views obesity as a disease. This position reflects the analysis done by the American Medical Association of the criteria for a disease and the fact that obesity fits these criteria. The criteria are:

- 1. An impairment of the normal functioning of some aspect of the body;
- 2. Characteristic signs or symptoms; and
- 3. Harm or morbidity.

The conclusion that obesity is a disease with multiple pathophysiological aspects, including genetic, environmental, physiological, and psychological factors, sets the framework for future efforts from many stakeholders to advance its treatment and prevention.

B. AACE plans to establish several strategies to meet a need for additional training for endocrinologists in obesity management;

C. AACE plans to develop a certifying procedure for endocrinologists who have successfully completed additional training programs; and

D. AACE plans to work with other organizations to develop additional efforts to combat obesity as a disease.

OBESITY AS A DISEASE

Obesity is found in nearly one-third of the US adult population and is currently defined as a body mass index (BMI) equal to or greater than 30 kg of body weight per meter squared of height. This arithmetical heuristic is a proxy for the relative quantity of adiposity and is used to predict and evaluate disease risk. Values corresponding to normal weight, overweight, and various classes of obesity are confounded by body frame and muscularity, sarcopenia in aging or disease, spinal deformities, physical disabilities, and transcultural differences. Other markers for excess body fat and body composition (eg, waist circumference, skin fold thickness, waist-to-hip ratio, waist-toheight ratio, bioelectrical impedance, and dual energy x-ray absorptiometry) are used in clinical practice and investigation, and each has relative advantages and disadvantages. While obesity research and clinical management may lack a universally optimal metric, there is copious epidemiologic evidence to support the association of excess body fat with risks for other primary disease states, such as type 2 diabetes mellitus (T2DM) and dyslipidemia. Perhaps the greatest limitation of any measure that relegates the diagnosis of obesity to the mere quantity of body fat is the failure to consider the impact of adiposity on physiological and metabolic processes that result in increased morbidity and mortality. So, the question remains: is obesity a primary disease state that involves more than just a quantitative excess of body fat?

In 1998, the AACE/American College Endocrinology Obesity Task Force issued a Position Statement on the Prevention, Diagnosis, and Treatment of Obesity (1). This statement reinforced that "Obesity is a complex, multifactorial condition characterized by excess body fat. It must be viewed as a chronic disorder that essentially requires perpetual care, support, and followup. Obesity causes many other diseases, and it warrants recognition by health-care providers and payers." On the basis of biomedical knowledge that has accumulated since that time and with a better understanding of the pathophysiology of obesity and its impact on the health of individuals and on society, AACE now strongly asserts that obesity is a primary disease, and the full force of our medical knowledge should be brought to bear on the prevention and treatment of obesity as a primary disease entity.

The contribution of lifestyle practices in the pathophysiology of obesity cannot be denied, and neither can the fact that molecular, genetic, and endocrine processes can create an obese phenotype. Many physicians have labeled obesity as a "disease" for more than 250 years, although many people refer to obesity as a "condition" or "health problem." There are a number of perspectives from which this question could be addressed (2,3). The most direct scientific approach for adjudicating whether a clinical construct is in fact a disease would be to first define the essential characteristics of what constitutes a human disease and then examine the scientific evidence that empirically addresses whether obesity meets these criteria. The American Medical Association has identified the essential criteria common to all definitions that constitute a disease (report 4 A-05 of the AMA Council on Scientific Affairs) (4). These definitions shared in common the following 3 essential characteristics of disease: (a) an impairment of the normal functioning of some aspect of the body; (b) that has characteristic signs or symptoms; and (c) results in harm or morbidity to the entity affected.

Obesity meets these 3 conditions. First, obesity is an altered physiological and metabolic state, with environmental, genetic, and hormonal determinants, which results in increased morbidity and mortality. Current data provide undeniable evidence for an obesity-centric model of disease with impairment of normal functioning including appetite dysregulation, abnormal energy balance, endocrine dysfunction including elevated leptin levels and insulin resistance, infertility, dysregulated adipokine signaling, abnormal endothelial function and blood pressure elevation, nonalcoholic fatty liver disease, dyslipidemia, and systemic and adipose tissue inflammation. Some aspects of obesity that lead to an impairment in body function are

anatomic and relate to the increase in body fat mass per se such as osteoarthritis, immobility, lymphedema and/or venous stasis, and to some extent sleep apnea. However, critical aspects may also be physiologic, such as the impact of body fat mass on insulin resistance and its associated trait complex with progression to T2DM and cardiovascular disease. Indeed, some have proposed "staging systems" for grading the effect of adiposity on the health of individuals as an approach for intensification of obesity therapy (5,6).

It is also clear that there are behavioral determinants of obesity, some of which are under the control of the individual such as wellness behavior, diet preferences, and physical activity, and other environmental factors that are outside of individual control such as the availability of fresh foods, environmental endocrine disruptors, and sociocultural attitudes and customs. However, obesity is also highly determined by genetic factors that comprise large subsets of at-risk alleles, each conferring a small relative risk, but which in aggregate predispose who will or will not become obese in an obesogenic environment (7). Other sets of overlapping polygenes determine the deleterious effect of adiposity on metabolism, insulin resistance, and progression to T2DM (8) and cardiovascular disease. Thus, like all diseases, obesity is an altered pathophysiological state, and its adverse effects on the health of the individual are the product of environment-gene interactions.

The second criterion for a disease is that it has characteristic signs or symptoms. With obesity, the primary abnormality is the increase in body fat as indicated, in most people, by an increase in the BMI. As discussed above, BMI has its limitations and neglects the extent to which any increase in adiposity adversely alters physiology, metabolism, and health (eg, blood pressure, glucose tolerance, lipids and lipoproteins). Nevertheless, obesity is readily identifiable clinically and has signs and symptoms pertaining to the physical accumulation of fat mass (joint pain, immobility, sleep apnea, low self-esteem, etc). It can also be considered that obesity has symptoms referent to altered metabolism once there is progression to end-organ disease such as T2DM and cardiovascular disease.

Finally, a disease results in harm or morbidity and there is no question that obesity is associated with harm. Both morbidity (9) and mortality (10,11) are increased. Morbidity can be directly related to the physical increase in fat mass and/or the physiological and metabolic derangements that are integral to obesity. It is argued that causality has not been established since this is beyond the reach of epidemiologic studies showing the association between obesity and morbid conditions; however, these arguments become less convincing with accumulating knowledge concerning the overlap between the pathophysiological processes provoked by obesity (inflammation, insulin resistance, and dyslipidemia) and the molecular pathogenesis of associated diseases such as T2DM and cardiovascular

disease. From the clinical perspective, it is most relevant that therapeutic interventions directed at reducing excess fat mass, whether by lifestyle intervention, pharmacotherapy, or bariatric surgery, can alleviate obesity-related morbidity and mortality (12-18). Therapies achieving weight loss can improve glycemic control in diabetes; reduce risk of T2DM, cardiovascular disease, and some cancers; and alleviate other obesity-related comorbidities such as osteoarthritis, sleep apnea, and polycystic ovary syndrome. The Centers for Medicare and Medicaid Services determined in November of 2011 (decision memo CAG-00423N) that the "evidence is adequate to conclude that intensive behavioral therapy for obesity, defined as a body mass index (BMI) 30 kg/m², is reasonable and necessary for the prevention or early detection of illness or disability and is recommended with a grade of A or B by the U.S. Preventive Services Task Force." Furthermore, it is clear that weight loss from lifestyle (12-15), medical therapies (12,16,17), and bariatric surgery (18) can dramatically reduce the progression to T2DM, reduce cardiovascular disease risk and mortality, decrease stroke, and reduce the incidence of cancer in women.

The conclusion that obesity is a disease represents a paradigm shift that stands in stark contrast to the notion that obesity simply results from the personal tendency to overeat or engage in a sedentary lifestyle. This latter perspective is commonly encountered in our society, as well as in medical circles and governmental policy-making bodies, and is reflected in patterns of health insurance coverage. To say that obesity is not a disease but rather a consequence of chosen lifestyle (ie, overeating and/or inactivity) is equivalent to saying that lung cancer is also not a disease because it was brought about by volitional cigarette smoking. It is the strong contention of AACE that the view of obesity as a behavioral decision is debunked by biomedical evidence. Accordingly, the new paradigm recognizing obesity as a primary disease state has salient social, political, economic, and transcultural implications. The classification of obesity as a disease will help mobilize society towards the importance of prevention and treatment, and enlist the aid of government, health care providers and payers, and scientific and professional organizations. The disease designation fosters change in attitudes and in the financial support needed for more intensive scientific investigation, drug discovery, resources for patient care, and the development of improved strategies for both prevention and treatment. In the end, it will require a collaborative and coordinated effort by physicians, scientists, pharmaceutical companies, health care payers, government, and patients to mobilize the efforts necessary to combat obesity, ameliorate the suffering of patients, and reduce the social costs of this disease.

Of particular concern is the recent evaluation of new obesity medications by the US Food and Drug Administration. While the safety of patients is paramount, no medication is without adverse effects and risk must be balanced against benefit. In evaluating obesity medications, it is important that the critical need for effective antiobesity medications be considered, along with the benefits that could be realized if these medications were available to health care providers to help their patients when indicated. Another concern is that failure to classify obesity as a disease leaves open the question of civil rights protection under the Americans with Disabilities Act of 1990 (19).

Another downstream implication of classifying obesity as a disease is that physicians and health care providers will be able to more effectively mobilize around health promotion, preventive medicine, and disease management. This includes universal screening of the general population; more aggressive case-finding of the subset of at-risk individuals; therapeutic programs directed at personalized treatment of obese patients; and a programmatic approach targeting children, adolescents, and families in the treatment and prevention of obesity. More physicians will need specialty training in obesity medicine. This discipline will require a comprehensive knowledge and experience base in metabolic diseases, with particular emphasis in diabetes and cardiovascular disease risk, areas where endocrinologists receive specialized training and are therefore well poised to play an important role. However, the successful cultivation of a health care system based on this reworked paradigm will necessitate dedicated, or formalized, obesity medicine training at all levels of medical education, and a certification process to ensure expertise, not just competency, in patient care. The discussion below outlines the positions of AACE on obesity medicine training and the role of the endocrinologist in combating obesity as a disease.

AACE PROPOSAL

Part 1: Obesity Medical Education

There is a greater need for formal structures of medical education primarily dedicated to the medical care of the obese patient. The current state is to subsume obesity medicine into curricula, didactics, research, and training in related fields, such as T2DM, hypertension, and cardiovascular disease, as well as passing mention in lectures in critical care medicine, gastroenterology, surgery, physical medicine, and psychiatry, among others. It is clear from recent research that the pathogenesis of obesity involves multiple distinct hormonal and metabolic processes intrinsic to the development and impact of obesity as a disease state and that there are strategies for treatment and prevention uniquely targeted to obesity. These considerations dictate that modules be specifically developed for undergraduate, graduate, and continuing obesity medical education and patient care. An emerging pattern of health care resources that focus on the care of the obese patient is found in bariatric surgery. Although bariatric surgery has successfully bridged basic research, clinical trials, and technologic innovation, it falls short of an envisioned obesity comprehensive care plan (similar strategy to the AACE Diabetes Comprehensive Care Plan [2]) encompassing short-term and long-term care of the obese patient and management of obesity complications. Further, it is clear that surgical interventions are impractical for, and may not be indicated in, substantial numbers of obese patients, including those with underlying cardiovascular disease and increased surgical risk (20). Endocrinologists and nutrition specialists trained in obesity medicine can best evaluate treatment options for obese patients and help to direct their long-term care.

AACE proposes a staged system for education and training in obesity medicine for clinical endocrinologists. The first stage will establish Web-based didactic and case-based educational programs in obesity medicine, which may be accredited for continuing medical education as needed, coupled with symposia at regional AACE chapter meetings and annual AACE national meetings. The second stage will establish a nucleus of clinical endocrinologists to create advanced learning programs in obesity medicine that incorporate the current basic and clinical evidence, as well as relevant patient management approaches. From a systems standpoint, it is hoped that following the successful implementation of this educational model, other disciplines and levels of medical education, as well as political and economic enterprises, will follow suit to create a culture and practice embracing the importance of obesity medicine.

Part 2: Obesity Medicine Certification

There have been several venues for certification in obesity medicine, bariatric medicine, and bariatric surgery, but these have been supplanted by the newly formed American Board of Obesity Medicine (formerly the American Board of Bariatric Medicine). The curriculum and examination are geared toward the general medical community and have been supported by several professional medical societies that are stakeholders in the battle against obesity. AACE, although recognizing the important effort of other societies, has elected to focus its efforts on the role and education of clinical endocrinologists, leading to expertise and certification within this internal medicine subspecialty. With today's understanding of obesity as a complex hormonal, neuronal, and metabolic disease with derangement of energy balance leading to multiple comorbidities, it is clear that highly trained and qualified endocrinologists can provide clinical leadership and mentoring in this area.

The treatment of obesity extends beyond simple weight loss and includes surveillance and treatment for obesity-related complications. It is important to consider that available and emerging therapies do not often achieve and maintain ideal body weight for patients, and a component

of overweight and obesity will often persist together with other risks for cardiometabolic disease. Obese patients at any stage commonly present with metabolic syndrome, prediabetes, T2DM, dyslipidemia, and cardiovascular disease, all of which are within the expertise domain of an endocrinologist. Furthermore, obesity can be caused by a variety of genetic disorders (eg, Prader-Willi syndrome, MC4R mutations) and hormonal disorders (Cushing disease), which underscores the complexity of the disease and the potentially unique role for the endocrinologist in that diagnostic process. Thus, endocrinologists are well equipped to provide leadership in the long-term care of obese patients in a manner that is oriented to reduce both morbidity and mortality. The certification process is an important logistical component toward ensuring sufficient expertise in obesity medicine in combination with existing expertise in endocrinology, metabolism, and diabetes. Moreover, obesity medicine education and certification should be integrated with effective obesity-friendly health care delivery systems, requisite preparatory physician training and possible credentialing processes, and subsequent clinical practice optimization.

AACE proposes development of a certification process for clinical endocrinologists after successful completion of a formalized AACE educational program in obesity medicine. This coordinated education and certification process would focus on the needs and special expertise of the clinical endocrinologist. This process will also produce highly skilled and capable leadership and educators in the care of obese patients and in the health care community.

Part 3: Professional Society Collaboration

It is obvious that obesity medicine has many stake-holders among medical specialties and their respective professional societies. Besides clinical endocrinologists, a list of professional stakeholders includes general internists, family medicine specialists, bariatric and metabolic surgeons, gastroenterologists, cardiologists, educators, and other allied health professionals. All have roles to play in a reinvigorated effort to combat obesity as a disease. AACE intends to collaborate with other professional societies, government, industry, and other organizations to effectively combat obesity on many levels. The role of the clinical endocrinologist will be better delineated, not only in how an Obesity Comprehensive Care Plan can be fashioned, but also how a multidisciplinary team approach can be exercised in the care of the obese patient.

AACE proposes a national collaboration among stakeholders in obesity patient care to foster a critical mass of expertise across specialties to advance an Obesity Comprehensive Care Plan. In addition to developing obesity medicine education and practice management tools specifically tailored for clinical

endocrinologists, AACE will also seek to codevelop and/ or participate in obesity medicine education, research, and social advocacy programs with other professional societies, government, and stakeholder groups.

Part 4: Advocacy for Social Change to Promote Antiobesity Strategies

With the recognition that obesity is indeed a disease, greater advocacy is needed. This should include increased recognition of the impact of the obesity epidemic, more effective and scientifically-based antiobesity legislation and health care policy, more critical data-driven evaluation of new antiobesity drugs by the US Food and Drug Administration in a manner that appropriately considers both risk and benefit, and the provision of public health activities addressing obesity. As more endocrinologists transition to the care of the obese patient under the new education and certification paradigm, there will be a need to provide guidance and up-to-date information related to practice management and reimbursement issues.

AACE will advocate for change to benefit patients with obesity and enhance the treatment and prevention of obesity as a disease. Efforts will be directed at the level of government, health care policy, scientific research, drug development, and public health. AACE proposes enhancement of its socioeconomic and legislative resources to maintain effective advocacy and stay abreast of developments in government, industry, and the health care system regarding obesity. AACE will optimize coding and reimbursement for obesity medicine practice.

DISCLOSURE

Dr. Jeffrey Mechanick has received honoraria from Abbott Nutrition for lectures and program development.

Dr. Alan Garber has served as a consultant for NovoNordisk, Daiichi Sankyo, Merck, Takeda, Santarus, LipoScience, Boehringer Ingelheim, Sekris, Lexicon, Halozyme, Tethys, and Vivus and has been a speaker for NovoNordisk, Merck, Santarus, and Daiichi Sankyo.

Dr. Yehuda Handelsman has received grants for research from Boehringer Ingelheim, ConjuChem, GlaxoSmithKline, Lexicon, NovoNordisk, sanofi, Xoma, and Tolerx; has served as a consultant for Amarin, Amylin, Daiichi Sankyo, Gilead, Halozyme, Janssen, LipoScience, Merck, NovoNordisk, sanofi, and Santarus; has served on the speakers' bureaus for AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Daiichi Sankyo, GlaxoSmithKline, Lilly, NovoNordisk, and Santarus; and has served as the associate editor for the *Journal of Diabetes* and as the immediate past president for the American Association of Clinical Endocrinologists.

Dr. Timothy Garvey has no multiplicity of interest to disclose.

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