



2014 AACE/ACE Consensus Conference on Obesity

Executive Summary

The AACE/ACE Consensus Conference on Obesity (CCO): Building an Evidence Base for Comprehensive Action convened March 23-25, 2014 in Washington, D.C. The premise of the conference was that by bringing together stakeholders in U.S. obesity care, representing the biomedical and public health models, new information would emerge to initialize a process to formulate actionable recommendations. Key findings of this conference include the need for: an improved definition of obesity; further research to refine the utility of a complications-centric clinical approach to obesity; better understanding of reimbursement mechanisms and the value associated with obesity prevention and management: increased nutrition and obesity education; and enhanced public awareness and health literacy. Next steps include deriving a more robust definition of obesity, translating these findings into actionable recommendations for individual patients that are likely to succeed, and developing logistics for effective implementation.

Analysis

The evidence base and conclusions derived from the 5-question, 4-pillar matrix served as discussion points for “among-pillar” moderated sessions. Information from these discussions was analyzed by writing committee members to generate the following statements.

Affirmed Concepts (AC) - Many concepts, with varying levels of validation, have been generally accepted by the scientific and medical communities, and also supported by AACE/ACE previously in treatment recommendations. These concepts were the subject of analysis at the AACE/ACE CCO and were discussed in terms of their accuracy, relevance, and utility. These concepts were affirmed, or slightly modified, and found to be consistent with the evidence base established at the AACE/ACE CCO. These ACs are included here since they are deemed, through consensus, to have sufficient potential to generate actionable recommendations.

AC.1. Obesity is a chronic disease. There was consensus that this precept is scientifically justified and critical to efforts to combat obesity.

AC.2. The AACE/ACE Obesity Algorithm should be implemented in patients with obesity. Safe and effective treatment modalities for overweight/obesity based on complications-centric risk stratification include intensive lifestyle intervention, meal replacements in the context of reduced calorie diets, pharmaceuticals, and surgery. Recommended team approaches utilize an expert in obesity, physician consultants as needed, and other health care professionals. Patients who are overweight are included in the AACE/ACE algorithm and may be situated on a physiological continuum of insulin resistance and/or adipocyte dysfunction that is associated with an increased risk for obesity and cardiometabolic disease.

AC.3. Lifestyle intervention is critical to an obesity comprehensive care plan. Lifestyle interventions include behavioral modification, healthy eating patterns, increased physical activity, and sleep hygiene. However, a greater degree of standardization of lifestyle intervention programs, more detailed recommendations regarding the components of therapy, as well as effective communications and community engagement, are needed for successful application and evaluation. Reimbursement for long-term and individualized, high-intensity structured lifestyle interventions is necessary, especially in the context of reducing disparities in health care accessibility.

AC.4. The obesogenic factors in the environment need to be reduced. The obese phenotype results from an interaction of the built environment and genotype. Efforts to reduce the obesogenic nature of our environment will require participation from stakeholders in the biomedical, government and regulatory, industry and economic, and society, education, and research pillars. These efforts include better nutritional messaging, more health literacy initiatives, public policy and public awareness and advocacy regarding the dangers of untreated overweight/obesity and the rewards of a healthy lifestyle and body. The role of more aggressive anti-obesity legislation requires further study.

AC.5. Primary and secondary prevention strategies are critically important. In addition to tertiary interventions, preventive strategies at early life stages are essential for a comprehensive action plan to combat obesity.

Emergent Concepts (EC) - New concepts emerged from multidisciplinary discussions of the evidence base at the AACE/ACE CCO. These ECs have not been validated, but are deemed through consensus to have sufficient potential to generate actionable recommendations.

EC.1. The definition of obesity needs to be improved. Obesity is currently defined as a chronic disease by many organizations, but nearly all discussions at the AACE/ACE CCO, involving all pillars and questions, centered on the need for a better definition of obesity as a chronic disease. The imprecision and uncertainties regarding a medically meaningful definition of obesity clearly emerged as a major impediment to concerted action and was responsible for a degree of immobilization across pillars. The analogy is a hub representing the definition of obesity as a central limitation that reaches out as spokes to each pillar and participating organizations to diminish the potential for concerted action. It was recognized that BMI, a component of the current definition, may be predictive for risk as a single metric, but as an anthropological measure may not reflect the impact of weight gain on the health or well-being of the individual. Furthermore, the predictive power of BMI varies among different ethnicities, body types, and specific complication targets. An improved medically relevant definition will facilitate optimization and access to lifestyle interventions, pharmaceutical development, regulatory agency processes, appropriate investigative research designs, education, public awareness and health literacy, and policy effectiveness. A more meaningful definition of obesity will require further study; however, the framework for a medical definition of obesity would consist of the continued use of BMI together with other anthropometrics (e.g., waist circumference) and an assessment of the presence and severity of obesity-related complications. For greater accuracy, such a definition would need to incorporate considerations of variables such as ethnicity and age.

EC.2. Regulatory, governmental, and insurance organizations require different thresholds of evidence based on specific mandates and decision processes. For instance, the CDC National Diabetes Prevention Program and similar programs can operate based on the extant evidence base, whereas the FDA requires additional structured evidence for many anti-obesity pharmaceuticals under evaluation. CMS requires sufficient evidence to demonstrate a benefit category, for example, USPSTF levels A or B for prevention modalities. Some private insurance carriers rely on evidence demonstrating health benefits, especially over a 3-5 year period. The emergent concept was that these particulars were impairing a more concerted and uniform action plan that would make effective treatment modalities available in a more consistent way among different population groups. Resolution of these issues is needed for a comprehensive action plan to combat obesity.

EC.3. Public awareness can change private insurance carriers' reimbursement strategies and health care coverage provided by employers. Social contracts, primarily between employers and private insurance carriers, can be modified to include reimbursement for components of obesity comprehensive care plans (structured lifestyle intervention, pharmaceuticals, and surgery as medically indicated), but are often denied to employees. This represents an important limitation in developing a

comprehensive obesity care plan. Change can be affected by greater public awareness and advocacy for obesity as a potentially dangerous chronic disease left untreated. Research is needed to examine the impact of covered weight loss therapy and prevention on employee health, health care expense, absenteeism, and morale and productivity.

EC.4. Intergenerational obesity must be prevented through intervention in children, including children 0-24 months old, in pregnancy to manage excessive maternal weight gain, and in reproductive age females. The transmission of risk for obesity is propagated via maternal weight gain to the *in utero* environment, promoting obesity in children, who become obese adults. A comprehensive action plan will require a preventive care model, with interventions applied to families and social groups, in addition to larger populations and individual patients.

EC.5. Understanding the value of obesity care is important for patients, physicians, payors, and employers. Value relates to effectiveness and both perceived and documented health benefits, in contrast to cost-effectiveness, which typically relates quality-of-life years based on cost. The value of different treatment and prevention modalities for obesity should receive greater emphasis in reimbursement decisions.

Key Findings (KF) -The writing committee has reviewed the AC and EC above and formulated KFs that can efficiently represent the results of the AACE/ACE CCO.

KF.1. Obesity is a chronic disease, and once diagnosed, should be managed using the AACE/ACE algorithm, which includes structured lifestyle intervention, meal replacements, pharmaceuticals, and surgery based on a complications-centric risk stratification model.

KF.2. A preventive medicine paradigm is necessary to improve outcomes in overweight/obesity and consists of structured lifestyle intervention, behavior change, and alterations in the built environment.

KF.3. Comprehensive overweight/obesity interventions producing improved outcomes require demonstration of value in a combined biomedical and public health model.

Rationale for a Consensus Conference on Obesity

Obesity rates have soared over the past 30 years, creating a global public health crisis. Data from two National Health and Nutrition Examination Surveys (NHANES) show that in 1990 obese adults made up less than 15% of the population in most U.S. states. Today, roughly 2 out of 3 U.S. adults are overweight or obese (69%), and 1 out of 3 adults are obese (36%). Global estimates suggest that 500 million adults are obese worldwide, and as many as 43 million preschool children are overweight or obese. Alarming, more than 1 billion adults are projected to be obese by 2030.

The impact of obesity on morbidity, mortality, and healthcare costs is staggering. Nearly 3 million adults die each year as a result of being overweight or obese. In the US, the annual cost of managing obesity has been estimated at approximately \$190.2 billion per year or 20.6% of national health expenditures. Other studies project costs up to \$270 billion. If these trends continue, health care costs related to obesity could reach \$957 billion by 2030. Obesity is estimated to add \$3371 (adjusted to 2012 dollars) annually to per-patient medical expenditures compared to patients who are not obese (Including \$1372 each year for inpatient services, \$1057 for outpatient services, and \$1130 for prescription drugs).

In the last 2 decades, accumulating data support the view that, like any other chronic disease, obesity has genetic, environmental, and behavioral determinants, which confer increased morbidity and mortality. The complications of obesity account for its adverse effects on mortality, morbidity, and quality of life, as well as the burgeoning social costs of the disease. Obesity-related complications can broadly be categorized as cardiometabolic, biomechanical, and other complications (Table 1).

Table 1: Cardiometabolic, Biomechanical, and Other Complications of Obesity

Cardiometabolic Disease	Biomechanical Complications	Other Complications
Cardiovascular disease	Disability/dismobility	Certain cancers
Dyslipidemia	Gastroesophageal reflux disease	Depression
Hypertension	Osteoarthritis	Gall bladder disease
Metabolic syndrome	Sleep apnea	Infertility
Non-alcoholic fatty liver disease	Stress incontinence	Social stigmatization
Prediabetes		
Type 2 diabetes		

In 2012, the American Association of Clinical Endocrinologists (AACE) published a position statement designating obesity as a disease and providing the rationale for this designation. Subsequently, AACE was joined by multiple organizations in submitting a proposition to the American Medical Association (AMA) to recognize obesity as a disease. In June 2013, following a vote by its House of Delegates, the AMA adopted a policy designating obesity as a chronic disease. This has enhanced opportunities to advance our understanding of the complex, multidimensional pathophysiology of obesity and provided an impetus to our healthcare system to develop more robust medical models for treatment and prevention.

In recent years, exciting advances have occurred in all 3 modalities used to treat obesity: lifestyle intervention, pharmacotherapy, and bariatric surgery. Clinical trials have established that lifestyle and behavioral interventions can produce and sustain weight loss, leading to the prevention and treatment of diabetes and improvements in cardiovascular risk factors. Principles embodied in these clinical trials have been translated into community-based programs for weight loss and incorporated into effective, structured treatment programs that can be remote or web-based, offered commercially, or used in multidisciplinary clinic-based programs.

Until recently, available pharmacotherapy options were limited, consisting of only single-agent phentermine, approved for short-term use, and orlistat. However, in 2012 the U.S. Food and Drug Administration (FDA) approved 2 new drugs as safe and effective for obesity, lorcaserin and phentermine/topiramate extended release (ER). In addition, 2 additional medications are currently being evaluated by the FDA for a weight loss indication (naltrexone/bupropion and high-dose liraglutide). Finally, bariatric surgical approaches have been developed and refined, and pre- and post-operative care practices improved. This has enhanced outcomes and reduced medical and surgical complications resulting from these procedures. These advancements in all treatment modalities for obesity have provided clinicians with improved tools to reduce morbidity and improve patient quality of life. In particular, it is clear that the combination of lifestyle intervention combined with pharmacotherapy can induce 5%-15% weight loss in the majority of patients; this is sufficient to substantially improve a large number of obesity-related complications.

The most commonly followed paradigm for obesity care, as well as FDA-sanctioned prescribing information for the use of obesity medications, index indications for treatment to anthropomorphic metrics such as weight and body mass index (BMI). In contrast, AACE has formulated a complications-centric approach, wherein the presence and severity of obesity-related complications are the primary determinants for selection of the treatment modality and intensity of weight loss therapy. Moreover, the primary endpoint of therapy is improvement in the obesity-related complications being treated by weight loss therapy, not a set decline in body weight. Other organizations such as the American Heart Association/American College of Cardiology/The Obesity Society and the American Society of Bariatric Physicians (ASBP) have also developed obesity care algorithms that take complications into account.

It is clear from the above discussion that society is experiencing an increased burden of patient suffering and social cost due to obesity. At the same time, we have a more advanced knowledge of pathophysiology pertinent to prevention as well as improved therapeutic tools. Old-order thinking that obesity is a lifestyle choice, allowing us to dismiss or ignore the need to implement a robust medical model for prevention and treatment, has failed us. These considerations compelled AACE to marshal evidence that could inform the development of an effective and comprehensive action plan to combat obesity. However, it was clear that such a plan would require the concerted action of a broad stakeholder base addressing a common evidence base. Using the analogy of a Greek temple, AACE viewed these stakeholders as constituting the 4 “pillars” needed to support a comprehensive strategy that could be represented by the temple’s pediment. Without the concerted participation of all 4 pillars, the pediment would fall to the ground (i.e., render the plan non-viable).

The four pillars and the constituencies that comprise each pillar who participated in the AACE Consensus Conference on Obesity are delineated in Table 2. The Biomedical pillar comprises professional organizations representing multidisciplinary health care professionals participating in the care of patients with obesity. The Government/Regulatory pillar includes groups that set policy for health care and disease prevention. The Health Care Industry pillar encompasses pharmaceutical companies developing medications for obesity, large employers concerned with the adverse health impact of obesity among their employees, and major payers or health care insurance companies. The Organizations, Education, and Research pillar also includes lay and professional organizations advocating for obesity, federal agencies sponsoring biomedical research, and medical educational organizations.

Table 2: Obesity Consensus Conference Pillar Participants

Biomedical	National Lipid Association American Psychological Association American College of Physicians American Association of Nurse Practitioners American Academy of Physician Assistants American College of Sports Medicine American Psychological Association American Academy of Pediatrics David Marrero, PhD, Indiana University School of Medicine Francesco Rubino, MD American Association of Nurse Practitioners American Society for Metabolic & Bariatric Surgery Academy of Nutrition and Dietetics American Psychiatric Association American Society of Bariatric Physicians
Government & Regulatory	Centers for Disease Control and Prevention US Food and Drug Administration, Office of Constituent Affairs US Department of Agriculture, Center for Nutrition Policy and Promotion Health Promotion and Disease Prevention, NYC Department of Health and Mental Hygiene Centers for Medicaid & Medicare Services Gregory Peterson, DO, FACP, American Association of Clinical Endocrinologists
Health Industry & Economics	US Food and Drug Administration, Office of Device Evaluation Takeda Pharmaceuticals U.S.A., Inc. Novo Nordisk Inc. GI Dynamics, Inc. Eisai Inc. Eric A. Finkelstein, PhD, MHA Novo Nordisk Inc. Bank of America IMS Health Takeda Pharmaceuticals U.S.A., Inc. Weight Watchers International Humana Cigna Aetna VIVUS, Inc.
Society, Education & Research	Solvieg Cunningham, PhD Association of Program Directors in Endocrinology, Diabetes & Metabolism STOP Obesity Alliance Accreditation Council for Graduate Medical Education Lillian Lien, MD, Medical Director, Duke Inpatient Diabetes Management Obesity Action Coalition American College of Cardiology American Diabetes Association National Kidney Foundation

The goal of the AACE-ACE-Consensus Conference on Obesity (CCO) was to develop the evidence base for a comprehensive action plan and to identify points of consensus along with alternative interpretations among constituencies within the 4 pillars. The intention was to have the broad range of stakeholders jointly examine the evidence from different perspectives and with different emphases on priorities. In this sense, the conference was emergent in nature and a process of joint discovery based in terms of the totality of viewpoints. This approach was critical since the action plan will ultimately require concerted action and cooperation among stakeholders based on a consensus interpretation of evidence. This process of “building the evidence base” is viewed as the first step. Subsequent meetings will be planned to translate these findings into actionable, specific recommendations deemed likely to succeed, and the third step will be to implement the comprehensive action plan.

Methods and Scope of Conference

The AACE Obesity Consensus Conference was initiated by a directive from the AACE President, followed by an approval vote by the AACE Board of Directors. A task force of AACE leadership was charged with conference planning. It was agreed that the conference goal was to build an evidence base towards developing a comprehensive action plan for the effective prevention and treatment of obesity. The first step was to identify the key stakeholders essential to the development of comprehensive solutions. These stakeholders were placed into 4 groups, represented by the four pillars. Extensive discussions and consultations were conducted regarding which participants to invite within each pillar, and formal invitations were submitted to the individuals and organizations listed in Table 2. The Biomedical Pillar provided expertise in evaluating data pertaining to the diagnosis of obesity, as well as medical models for effective treatment and prevention. The Government/Regulatory Pillar was qualified to evaluate policies and practices regarding the effective prevention and treatment of obesity. The Health Care Industry Pillar was selected for their ability to address the efficacy of treatment options, whether therapy was being optimally utilized to benefit patients with obesity, and how this could be accomplished in a cost-effective manner. The Organizations/Education/Research Pillar was able to identify mechanisms by which research could be funded to fill knowledge gaps and to provide input on how to train the next generation health care professionals in the treatment and prevention of obesity.

To establish and organize the evidence base, the task force established 5 critical questions (Table 3), submitted ahead of the conference to participants in each of the pillars. Prior to the conference, all participants provided written answers to the questions and were requested to provide data, published references, and other relevant information in support of their answers. All responses were collated by AACE staff and disseminated to all participants in the weeks leading up to the conference. This process enabled participants across pillars to review and interpret the same data both prior to and in the context of the conference.

Table 3: Five Critical Questions: AACE-ACE Obesity Consensus Conference

Question 1	What is obesity?
Question 2	What options are available for obesity management?
Question 3	What is the optimal use of therapeutic modalities?
Question 4	Can the optimal framework be cost-effective?
Question 5	What are the key knowledge gaps, and how can they be filled?

The AACE Obesity Consensus Conference on Obesity took place March 22-23, 2014 in Washington, DC at the JW Marriott Hotel. The conference agenda is outlined in Figure 1.

Figure 1: AACE Obesity Consensus Conference Agenda

SUNDAY, MARCH 23 2014	
GENERAL SESSION—KEYNOTE SPEAKERS	
MODERATOR: DR. W. TIMOTHY GARVEY	
7:00 AM – 8:00 AM	Registration
8:00 AM - 8:10 AM	Welcome and Introductions Dr. Jeffrey I. Mechanick, AACE President, Obesity Consensus Task Force Co-Chair
8:10 AM - 8:45 AM	Conference Overview & AACE Perspective: “Obesity as a Disease” - Dr. W. Timothy Garvey, Obesity Consensus Task Force Chair
8:45 AM - 9:30 AM	“Building a Consensus: Evidence-Based Long-Term Weight Management” - Dr. John Foreyt, Director, Behavioral Medicine Research Center at Baylor College of Medicine
9:45 AM - 10:30 AM	“Making the Healthy Choice the Easy Choice: Working with Industry to Reduce Childhood Obesity” - Mr. Lawrence Soler, CEO of the Partnership for a Healthier America
10:30 AM - 11:15 AM	“Obesity: Where Do We Go From Here?” - Dr. Patrice Harris, American Medical Association Board of Trustees
11:15 AM - 11:45 AM	Summary and Next Steps Dr. W. Timothy Garvey, Chair
PILLAR BREAKOUT SESSIONS	
12:45 PM - 5:00 PM	Biomedical
	Government & Regulatory
	Health Industry & Economics
	Organizations, Education & Research
MONDAY, MARCH 24, 2014	
PILLAR FORUM	
8:00 AM - 8:10 AM	Welcome Dr. Timothy Garvey, Chair
8:10 AM – 9:00 AM	Question 1: What is Obesity? Dr. Alan J. Garber, Co-Chair
9:00 AM - 9:50 AM	Question 2: What Options are Available for Obesity Management? Dr. W. Timothy Garvey, Chair
10:05 AM - 10:55 AM	Question 3: What is the Optimal Use of Therapeutic Modalities? Dr. W. Timothy Garvey , Chair
10:55 AM – 11:45 AM	Question 4: Can the Optimal Framework be Cost-Effective? Dr. Jeffrey I. Mechanick, Co-Chair
11:45 AM - 12:35 PM	Question 5: What are the Knowledge Gaps and How Can They Be Filled? Dr. Jeffrey I. Mechanick, Co-Chair
12:35 PM - 1:00 PM	Conclusion Dr. W. Timothy Garvey, Chair
1:00 PM - 5:00 PM	Writing Committee Convenes

The conference began with introductory remarks from the AACE president (Dr. Mechanick), a summary of AACE’s position statement on obesity as a disease and its complications-centric treatment algorithm (Dr. Garvey), and 3 keynote talks from national leaders in obesity. Pillar breakout sessions were

scheduled on the afternoon of the first day. During these breakout sessions, participants within each pillar individually presented their answers to each of the 5 questions using oral statements, hardcopy handouts, and/or slide presentations. Every participant was given up to 10 minutes to respond to each question. This was followed by general discussion and debate, moderated by the co-chairs. For each question, the effort was made to establish points of consensus among participants, as well as to identify alternative viewpoints and knowledge gaps requiring additional research. The proceedings were both recorded and transcribed. To capture salient aspects and conclusions in real time, a team of medical writers and conference leaders integrated information and discussions.

On the morning of the second day, the pillars met together for “among-pillar discussions” so all participants could evaluate and debate the conclusions reached by the individual pillars. The co-chairs assigned to each pillar briefly summarized the points of consensus and alternate views, followed by robust discussion of the evidence pertinent to each question, involving all participants. This facilitated the emergence of consensus across pillars, needed to develop a concerted action plan. Again, the proceedings were recorded, transcribed, and summarized by onsite medical note-takers.

Immediately after the conference, a primary writing team analyzed the meeting’s transcripts and completed this document summarizing the conference proceedings, along with points of consensus and alternative views. The writing committee identified points of affirmation where the data and related discussions supported previously accepted or validated practices. In addition, new points of emergence arose from the dynamic and multi-disciplinary nature of the conference. Both the affirmative and emergent conclusions were sufficient to form the basis for actionable recommendations. Thus, the goal of “building an evidence base” for a comprehensive action plan was achieved. To translate this evidence base via the development of recommended interventions and protocols, subsequent interactions involving the pillar participants are planned, followed by implementation.

Conclusion

This immediate AACE/ACE CCO deliverable includes evidence from 4 pillars of stakeholders as part of a composite biomedical and public health disease model of obesity care. The evidence has been organized into 5 relevant and pragmatic questions. Analysis of the evidence base has produced statements corresponding to affirmed concepts, emergent concepts, key findings, and a final summation. AACE plans to translate this body of information into actionable recommendations that will strategically and efficiently provide net benefit and value to individual patients requiring comprehensive anti-obesity management. Subsequently, AACE plans to devise implementation logistics for these specific recommendations to realize successful anti-obesity care.