Clinical Practice Guideline for the Behavioral Treatment of Obesity and Overweight in Children and Adolescents

from the Guideline Development Panel (GDP) for Obesity Treatment of the American Psychological Association (APA)

Draft

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GDP Members:

Maria M. Llabre, Chair

Jamy Darone Ard, Vice-Chair

Gary Bennett

Phillip J. Brantley

Barbara Fiese

Jane Gray

Patty Nece

Michele Polfuss

Hollie Raynor

Delia West

Denise Wilfley

APA Guidelines Staff:

Lynn Bufka

Raquel Halfond

Howard Kurtzman

Abstract- Summarize objective, Methods, Results, & Recommendations (Staff)

[To be drafted when document is submitted for publication.]

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Disclaimer

This guideline is intended to be aspirational and is not intended to create a requirement for practice. It is not intended to limit scope of practice in licensing laws for psychologists or for other independently licensed professionals, nor limit coverage for reimbursement by third party payers.

The term guidelines refers to statements that suggest or recommend specific professional behavior, endeavor, or conduct for psychologists. Guidelines differ from standards in that standards are mandatory and may be accompanied by an enforcement mechanism. Thus, guidelines are aspirational in intent. They are intended to facilitate the continued systematic development of the profession and to help assure a high level of professional practice by psychologists. Guidelines are not intended to be mandatory or exhaustive and may not be applicable to every professional and clinical situation. They are not definitive and they are not intended to take precedence over the judgment of psychologists. Clinical practice guidelines provide research-based recommendations for treatment of particular conditions (APA, 2015).

In considering the present guideline recommendations, the APA Obesity Guideline Development Panel (GDP) endorses the following statement from the British National Institute for Health and Clinical Excellence (NICE), *"The recommendations in this guideline represent the view of NICE [APA], arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The application of the recommendations in this guideline is not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian,"* (2009).

Executive Summary

Introduction

Over the past five decades, rates of childhood obesity have increased almost four-fold (Ogden, Carroll, Kit, & Flegal, 2014). Moreover, there are differences in prevalence rates by race (American Academy of Family Physicians, 2014; Ogden, Carroll, Fryar & Flegal, 2015) and socioeconomic status (August et al., 2008; Ogden, Lamb, Carroll & Flegal, 2010), with higher rates in minority and low socioeconomic status groups. Obesity in children can result in both immediate and long-term health risks, such as type 2 diabetes, asthma, hypertension, hyperlipidemia, nonalcoholic fatty liver disease, polycystic ovarian syndrome, obstructive sleep apnea and musculoskeletal/joint dysfunction (Barlow, 2007; Bass & Eneli, 2015). Obesity can also negatively impact children's mental health and psychosocial development (Small & Aplasca, 2016). Children with overweight or obesity may experience weight-based stigmatization.

Evidence-based clinical practice guidelines are intended to assist the healthcare system in providing appropriate care, improving quality and consistency of care, and reducing mortality and morbidity. Guidelines are particularly needed to address care of children and adolescents with overweight or obesity in order to prevent the onset of more serious health problems.

Scope

This guideline is intended to provide treatment recommendations regarding the use of family-based multicomponent behavioral interventions for overweight (body mass index ≥ 85 % percentile for age and gender) and obesity (body mass index ≥ 95 % percentile for age and gender) in children and adolescents, ages 2-18 years, based on a systematic review of the evidence. The panel commissioned a systematic review conducted by Kaiser Permanente Research Affiliates Evidence-based Practice Center (O'Connor, Burda, Eder, Walsh, & Evans, 2016), which served as the evidence base for drafting its recommendations. This guideline

addresses the efficacy of family- based multicomponent behavioral interventions in reducing and maintaining change in age/sex standardized BMI. It also reviews how selected intervention characteristics and strategies, as well as patient and family sociodemographic characteristics and patient adherence, engagement, and retention might impact these interventions and results. This guideline does not address other treatments for overweight or obesity, screening or assessment for overweight or obesity and related conditions, treatment follow-up, prevention of overweight or obesity, costs of treatments, pharmacological or surgical interventions, or availability of care (see rationale for scope pp. 23).

Key Questions

The panel considered the following five key questions:

1. In children and adolescents with overweight or obesity, do family-based multicomponent behavioral interventions reduce and maintain change in age/sex- standardized BMI?
2. What is the impact of selected characteristics of family-based multicomponent behavioral interventions (dosage of contact, setting, interventionist qualifications, mode of delivery, use of multidisciplinary team, involvement of psychologist, cultural tailoring) in the management of age/sex-standardized BMI? Specifically:
    a. Are these characteristics associated with the efficacy of the interventions?
    b. What is the comparative effectiveness of these characteristics?
3. How do selected patient and family sociodemographic characteristics (child's age, severity of adiposity, parental obesity, race, socioeconomic status) affect family-based multicomponent behavioral interventions? Specifically, are different strategies used or needed for families with different sociodemographic characteristics?
4. What is the impact of selected strategies of family-based behavioral interventions (goals and planning, comparison of outcomes, self-monitoring of behavior, self-monitoring of outcome, reward and threat, stimulus control, modeling of healthy lifestyle behaviors by parents, motivational interviewing, general parenting skills [e.g., positive parenting] or

family conflict management) in the management of age/sex-standardized BMI? Specifically:

   a. Are these strategies associated with the efficacy of the interventions?
   b. What is the comparative effectiveness of these strategies?

5. What is the effect of patient adherence (e.g., percentage of homework completed, percentage of sessions attended), engagement, and retention on BMI outcomes? Specifically:

   a. What interventions or intervention characteristics and strategies are associated with these factors?
   b. What levels of patient adherence, engagement, and retention are associated with improved efficacy of the interventions?

This guideline does not address any of the following:

1. Screening for overweight or obesity, treatments other than family-based multicomponent interventions, assessment of associated conditions, or follow-up after treatment.
2. Prevention of overweight or obesity.
3. Costs of treatments.
4. Availability of care.

Recommendations

The panel recommends the following:

1. For child and adolescent patients with overweight or obesity, the panel strongly recommends the provision of family-based multicomponent behavioral interventions, with a minimum of 26 contact hours, initiated at the earliest age possible.

There was insufficient evidence to make specific recommendations for subgroups of children or adolescents based on gender, race/ ethnicity, or socioeconomic status. Furthermore, there was

insufficient evidence to determine whether specific intervention characteristics or strategies were associated with greater adherence, engagement, or retention. There was also insufficient evidence to determine whether patient adherence or population characteristics other than child's age were associated with efficacy. The evidence supports family-based multicomponent behavioral interventions that address behavior change, diet and physical activity with sufficient intensity. Within this framework which includes all components, providers have flexibility in the specific strategies used to accomplish change.

Process and Method

APA's Advisory Steering Committee issued a call for nominations (including self-nominations) for individuals to serve as panel members from a variety of backgrounds (consumer, psychology, psychiatry, general medicine) with content knowledge in the area of obesity or methodological expertise in systematic reviews or treatment research. Conflicts of interest (financial and non-financial) were considered and managed both during panel member selection and throughout the guideline development process.

After engaging in a discussion of scoping and review of currently existing guidelines, the panel decided to focus on widely recommended family-based multicomponent behavioral interventions for children and adolescents. Further, the panel decided to focus on body mass index (BMI) and standardized BMI (zBMI), and not weight loss as some children may need to stop gaining weight while continuing to grow to return to a healthy weight range, and serious adverse events as the critical outcomes. However, the lack of information on serious adverse events in the articles resulted in the panel having insufficient empirical data on this outcome and relying heavily on lower quality evidence (clinician and consumer input) in this domain. The panel commissioned a systematic review to address questions related to efficacy of key strategies of multicomponent behavioral interventions for children and adolescents (O'Connor, et al., 2016) which served as the evidence base for drafting its recommendations. Additional

information regarding harms/burdens of care and patient values and preferences for care was derived from the professional literature and panel member experience.

Following recommendations from the Institute of Medicine (2011a) and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group (Guyatt et al., 2011), the panel considered four factors as it drafted recommendations: 1) overall strength of the evidence; 2) the balance of benefits vs. harms/burdens; 3) patient values and preferences; and 4) applicability (generalizability across populations, interventions, comparators, outcomes, timing, and settings). Based on the combination of these factors, the panel made a strong or weak recommendation for or against the treatment or treatment strategy or made a statement that there was insufficient evidence to be able to make a recommendation. The panel used a *Grid* to document its decision-making process for each recommendation. A copy of the Grid is available at (http://apacustomout.apa.org/commentPracGuidelines/Practice/Grid%20for%20Obesity%20GDP%20Recommendations%20for%20posting.pdf).

Conclusion

While the panel recommends family-based multicomponent interventions of 26 or more contact hours, there was insufficient evidence for the panel to make recommendations pertaining to specificity such as type of setting or provider, race and ethnicity of patients, and socioeconomic status. Further, the panel only examined the outcome of BMI/zBMI, as that was of critical interest and few other outcomes of interest (such as quality of life, change in emotional functioning) were consistently reported; thus, other outcomes that might have resulted from the intervention are not captured in this document. Health care providers are encouraged to help facilitate awareness of childhood obesity among parents, address barriers to treatment with families, advocate for financial coverage of treatment, and to treat children and adolescents with overweight or obesity and their parents/guardians in a non-stigmatizing/non-judgmental manner.

The recommendations in this guideline are similar to those of other health organizations. However, the review and conclusion that there was insufficient evidence that setting, interventionist qualifications, mode of delivery, use of multidisciplinary team including involvement of a psychologist, or cultural tailoring, in the implementation of family-based multicomponent behavioral interventions, had independent effects on standardized body mass index (zBMI) is a contribution to this arena. There were several limitations identified in the systematic review underlying this guideline. Limitations include a lack of information about the amount of adiposity reduction needed in children and adolescents to improve certain other aspects of health and the focus on only BMI as an outcome. It is possible that other outcomes could show improvement (e.g., diet quality, physical activity, and psychosocial outcomes). Frequently, race and ethnicity as well as socioeconomic status data were not reported in published studies, making it difficult to determine whether outcome disparities occur across SES or race and ethnicity, which may be a particularly critical question given the significantly higher prevalence of overweight and obesity among Hispanic and black youth. In addition, there was insufficient information in the review to address two key questions (what is the impact of selected strategies of family-based behavioral interventions in the management of age/sex-standardized BMI and what is the effect of patient adherence, engagement, and retention on the efficacy of intervention). There was also a lack of information on potential harms of interventions, although behavioral interventions are generally viewed as not harmful.

Clinical Practice Guideline for the Behavioral Treatment of Obesity and Overweight in Children and Adolescents

from the Guideline Development Panel (GDP) for Obesity Treatment of the American Psychological Association (APA)

Scope of the Guideline

The scope of this clinical practice guideline is on behavioral weight management for children and adolescents between the ages of 2 and 18 years with overweight or obesity as defined based on the Centers for Disease Control and Prevention BMI for Age and Gender growth charts. Given recommendations provided by the USPSTF in 2010 and 2017, and consistent with statements or guidelines from other health organizations (see Appendix D), family-based, multicomponent behavioral interventions, including both diet and a physical activity or sedentary behavior (screen time) components, have shown the most promise in improving weight status in children and adolescents with overweight or obesity. Additionally, these programs are accepted as initial interventions due to the perceived reluctance of families and providers to begin weight management with children and adolescents with either medication or surgery, given the limited information about long term impact or potential for adverse events. However, relatively little is known about the efficacy of specific characteristics of these multicomponent interventions or their efficacy for different subgroups of children and adolescents.

The panel considered the most recent systematic review in this area with a similar scope (Janicke et al., 2014) and determined there was a need to update and expand the information on efficacy studies. Earlier reviews and guidelines did not specify factors that may be important for understanding how to successfully implement an intervention, who may benefit most from intervention, what strategies are most efficacious, or areas of patient engagement needed for

successful outcomes. Therefore, to enhance understanding of clinical implementation of a family-based, multicomponent behavioral intervention, the scope of this effort included an examination of evidence including comparative effectiveness studies that would inform implementation characteristics, child/family moderators, intervention strategies, and patient engagement to provide recommendations important for clinical implementation of the intervention. The panel commissioned Kaiser Permanente Research Affiliates Evidence-Based Practice Center to conduct a systematic review of the evidence to address these questions and based this guideline on that review (O'Connor, et al., 2016). The guideline does not address other possible interventions. The intended users of this document include psychologists, other health and mental health professionals, students/ training programs, consumers, families of consumers, policy makers, and the public.

Summary of Recommendations of the APA GPD for the Treatment of Overweight and Obesity in Children and Adolescents

The panel recommends the following:

1. For child and adolescent patients with overweight or obesity, the panel strongly recommends the provision of family-based multicomponent behavioral interventions, with a minimum of 26 contact hours, initiated at the earliest age possible.

The Panel was unable to make recommendations on the following:

1. There was insufficient evidence to determine the comparative effectiveness of selected strategies of family-based multicomponent behavioral interventions, including goals and planning, comparison of outcomes, self-monitoring of behavior, self-monitoring of outcome, contingent reward or threat, stimulus control, modeling of healthy lifestyle behaviors by parents, motivational interviewing, or parenting skills training.

2. There was insufficient evidence to determine whether specific intervention characteristics or strategies were associated with adherence, engagement, or retention. Higher attendance was associated with greater efficacy but there was insufficient evidence to determine whether adherence (beyond attendance) was associated with efficacy.

3. There was insufficient evidence to determine whether specific intervention strategies were more effective with patients or families having specific characteristics. Other than age, there was either no association or insufficient evidence[1] to determine whether population characteristics were associated with outcome.

Thus, providers have flexibility in selecting an efficacious family-based multicomponent behavioral intervention program that addresses behavior change, diet and physical activity of sufficient intensity with strategies used to accomplish change appropriate for particular patients and local implementation needs.

[1] Participant race/ ethnicity, severity of adiposity and parental obesity status were not associated with outcome. There was insufficient evidence to determine whether socioeconomic status was associated with outcome.

Table 1: Summary of Recommendations of the APA Guideline Development Panel for the Treatment of Obesity

Family-Based Multicomponent Interventions	**Strength of Recommendation**
For child and adolescent patients with overweight or obesity, the panel strongly recommends that clinicians provide: • family-based multicomponent behavioral interventions with at least 26 contact hours initiated at the earliest age possible.	Strong For
Comparative Effectiveness of Components	
For child and adolescent patients with overweight or obesity, the panel concludes that there is insufficient evidence to recommend for or against clinicians offering any selected strategies of family based multicomponent behavioral interventions over another, including: • goals and planning • comparison of outcomes • self-monitoring of behavior • self-monitoring of outcome • contingent reward or threat • stimulus control • modeling of healthy lifestyle behaviors by parents • motivational interviewing • parenting skills training	Insufficient
For child and adolescent patients with overweight or obesity, the panel concludes that there is insufficient evidence to determine if specific intervention characteristics or strategies are associated with adherence, engagement, or retention, or if adherence was associated with efficacy.	Insufficient
For child and adolescent patients with overweight or obesity, the panel concludes that there is insufficient evidence to determine whether specific intervention strategies were needed with patients or families having specific characteristics.	Insufficient
For child and adolescent patients with overweight or obesity, the panel concludes that there is either no association or insufficient evidence to determine whether other population characteristics other than age were associated with outcome.	Insufficient

How these recommendations compare to recommendations in other obesity guideline documents is addressed on pages 19-24.

People-first Language

Throughout the document the panel refers to the target population as “persons with obesity” so as to separate the individual from the condition.

Introduction to the Topic

Overview of Problem, Healthcare Burden

Obesity is defined as body mass index (BMI) ≥ 95th percentile while overweight is defined as BMI ≥ 85 % percentile based on the Centers for Disease Control growth curves for age and gender. Childhood obesity rates have increased in the United States in the past five decades. In the 1960s the prevalence of obesity was approximately 4% in 6-11 year olds and 5% in those 12-19 years old; however, by 1994, the prevalence had increased to 11% for both age groups (Ogden, 2002). As of 2014, 17% of youth (ages 2-19 years) had obesity (Ogden et al., 2014). The prevalence of obesity increases with age. Preschool age children (2-5 years) have the lowest prevalence at 8.9%, increasing to 17.5% for children 6-11 years old, and 20.5% for adolescents (12-19 years) (Ogden et al., 2015). When including overweight statistics, 31.8 % of youth (ages 2-19 years) have overweight or obesity (Ogden et al., 2014).

In addition to differences by age group, there are also differences in obesity prevalence by race and ethnicity. Overall, non-Hispanic white and Asian youth have a significantly lower prevalence of obesity (14.7% and 8.6% respectively) compared to non-Hispanic black (19.5%) and Hispanic youth (21.9%) (Ogden et al., 2015). The race and ethnicity pattern of obesity was similar for female children, with Asian females having the lowest observed prevalence at 5.3% compared to 15.1% for non-Hispanic white females, 20.7% for non-Hispanic black females and 21.4% in Hispanic females (Ogden et al., 2015). For male children, Asians and non-Hispanic

whites have a lower rate of obesity (11.8% and 14.3% respectively) compared to non-Hispanic black (18.4%) and Hispanic males (22.4%) (Ogden et al., 2015).[2]

Childhood obesity prevalence also varies based on the parents' educational level and socioeconomic status. For example, in a study of data from 1999-2010, the prevalence rates of obesity among children with an adult head of household who completed college were nearly half the rates (9% for females, 11% for males) as those with an adult head of household who did not complete high school (19% for females, 21% for males) (May, Freedman, Sherry, & Blanck, 2013). In relation to household income, obesity prevalence typically has an inverse relationship with income; however, this relationship is found more consistently in non-Hispanic whites compared to non-Hispanic black and Hispanic youth (Freedman, Ogden, Flegal, Khan, Serdula, & Dietz, 2007). However, while low income children and adolescents are more likely to have obesity than their higher income counterparts, the relationship is not consistent across racial/ ethnic groups and it should be noted that most children and adolescents with obesity are not low income.

The burden of obesity poses some immediate and longer-term health risks for children. There are a number of negative medical consequences due to obesity—many of which increase as a function of the severity of obesity. These health effects include type 2 diabetes, hypertension, hyperlipidemia, asthma, polycystic ovarian syndrome, and nonalcoholic fatty liver disease (Pulgaron, 2013). More severe obesity can lead to obstructive sleep apnea and musculoskeletal/joint dysfunction (Bass & Eneli, 2015). In the longer term, children with obesity have a higher probability of having obesity as adults, and many of the comorbid conditions are associated with a prolonged history of obesity (Goldhaber-Fiebert, Rubinfield, Bhattacharya, Robinson, & Wise, 2013; Singh, Mulder, Twisk, Mechelen, & Chinapaw, 2008). As children reach adolescence, an elevated BMI becomes increasingly predictive of risk of obesity (BMI ≥

[2] No data were reported for other racial/ ethnic groups, such as Native Americans.

30 kg/m^2) later in life (Singh et al., 2008). For black and white males who have a BMI at or above the 85th percentile (overweight) at the age of 15, 56.6% and 59.2% respectively, are predicted to have obesity in their early 40's. For black and white females who have a BMI at or above the 85th percentile at the age of 15, the estimate is that 89.4% and 78.3%, respectively, are predicted to have obesity in their early 40's (Goldhaber-Fiebert et al., 2013). The higher probability of obesity in adulthood portends worse health outcomes later in life. For instance, it is estimated that over the next 40 years, those younger than 20 years old with obesity may experience an increase in the prevalence of type 2 diabetes of 49% (Imperatore et al., 2012).

Obesity can also have deleterious effects on mental health and psychosocial development in children. Compared to children who have a healthy weight, those with obesity have higher rates of depression, social isolation, low self-esteem, and poorer quality of life (Small & Aplasca, 2016). Weight-based stigmatization may play an important role in these outcomes. Children with overweight or obesity experience pervasive and often unrelenting weight stigmatization from an early age (Puhl & Latner, 2007; Harrist, Swindle, Hubbs-Tait, Topham, Shriver, & Page, 2016). Indeed, weight-based bullying is more prevalent than bullying based on race, sexual orientation and religion (Puhl, Latner, O'Brien, Luedicke, Forhan, & Danielsdottir, 2016). Overweight youth experience significantly more bullying than their peers who are of a healthy weight (Van Geel et al., 2014), with the severity of bullying and stigmatization increasing as weight increases (Puhl, Luedicke, & Grilo, 2013). Sources of stigmatization include peers, parents, teachers, coaches and strangers (Puhl et al., 2013). Weight stigmatization can take many forms, including teasing, ignoring, excluding, or rejecting the individual; and physical or verbal harassment (Harrist et al., 2016; Schvey, Puhl, & Brownell, 2011). Although childhood obesity has become far more commonplace, weight based stigmatization remains pervasive (Lumeng, Forrest, Appugliese, Kaciroti, Corwyn, & Bradley, 2010).

Current Guidelines for Treatment of Childhood Obesity

The need for evidence-based recommendations for the treatment of overweight and obesity in children and adolescents has been recognized for over two decades. In 1997, the Department of Health and Human Services Health Resources and Service Administration convened an expert committee to develop recommendations on the assessment and treatment of childhood obesity (Barlow & Dietz, 1998). However, their recommendations, published in 1998, were predominantly developed from consensus reached by the expert committee, with few of the recommendations for assessment and intervention being evidence-based, due to a lack of published research in the area.

In 2005, the American Medical Association, the Health Resources and Service Administration, and the Centers for Disease Control and Prevention (CDC) convened a new expert committee so that new recommendations could be developed for childhood obesity (Barlow, 2007). As the research base in the area of childhood obesity had expanded, the committee relied primarily on research evidence but, where evidence was lacking, also relied on clinical experience to provide practitioners with practical guidelines for the treatment of obesity in childhood. While the recommendations were developed mostly from research, a systematic review was not conducted to inform the guidelines. Instead, the writing groups of the committee broadly rated the evidence as being consistent, mixed, or suggestive. Furthermore, these practical guidelines provided recommendations in all areas of care for childhood obesity. Thus, when evidence in a considered area was lacking, the writing groups took into account extant literature, clinical experience, other health benefits and harms, and feasibility of implementation in making the recommendations.

These guidelines, published in 2007, propose a staged-approach to treatment (Spear, Barlow, Ervin, Ludwig, Saelens, Schetzina, & Taveras, 2007). The authors of the report acknowledged that while the components of the stages may be supported by evidence, the staged-approach had not been evaluated, and therefore the staged aspect is not evidence-

based. This approach contains four stages: 1) Prevention Plus (healthy lifestyle changes), 2) structured weight management, 3) comprehensive multidisciplinary intervention, and 4) tertiary care intervention. The stages are recommended to be implemented in children starting at the age of two years, when the BMI is $\geq$ 85th percentile. Prevention Plus starts with recommending changes in a few dietary (e.g., increase fruits and vegetables, decrease sugar sweetened beverages), physical activity, and/or screen-based (e.g., television watching) behaviors; incorporating the family into making these changes; using behavioral strategies in support of the changes; and having monthly assessments. Each sequential stage is to be implemented if the child's weight status does not improve after 3 to 6 months of active treatment at the current stage. The intervention increases in intensity through the stages in five ways: 1) enhanced dietary structure; 2) greater use of a broader range of behavioral strategies for assisting with changing diet, activity, and screen-based behaviors; 3) increased frequency of contact; 4) greater use of specialists trained in the intervention, as well as the use of professionals from across multiple disciplines; and 5) the addition of medication and/or surgery to the intervention.

When the second expert committee was convened in 2005, the United States Preventive Services Task Force (USPSTF) had just published a systematic review (Whitlock, Williams, Gold, Smith, & Shipman, 2005) on screening and interventions for childhood overweight, which found insufficient evidence to recommend for or against routine primary care screening for overweight in children and adolescents (an "I" recommendation) (US Preventive Services Task Force, 2005). This rating was due to the finding that the efficacy of behavioral counseling or other primary care–relevant interventions in childhood obesity was not clear. In 2010, the USPSTF updated their systematic review and examined primary care–relevant behavioral and pharmacologic weight management interventions for children aged 2 to 18 years who had overweight or obesity. Behaviorally-based interventions were defined as interventions that targeted changes in diet and/or physical activity, often involved parents or the entire family, and included cognitive and behavioral techniques to assist with changing diet and activity (Whitlock,

O'Connor, Williams, Beil, & Lutz, 2010). Pharmacological interventions were considered adjunctive interventions to behaviorally-based interventions, but only for adolescents with severe obesity. Bariatric surgery as an intervention was considered out of the scope of the review.

Results of the systematic review found that the available research had been conducted in children aged 4 to 18 years, with no study implemented in children under the age of 4 years (Whitlock et al., 2010). Comprehensive behavioral interventions that included a diet and activity focus, involved the family, and used behavioral strategies with contact time of 26 to 75 hours were the most efficacious approach, with weight improvements at 12 months favoring behavioral intervention. Two medications used as adjunctive therapy to behaviorally-based interventions found small (orlistat) or moderate (sibutramine) improvements in weight status in adolescents who had obesity and only when on active medication. Based on the results of the review, the USPSTF recommended that clinicians screen children aged 6 to 18 years for obesity and offer or refer these children to intensive counseling and behavioral interventions to promote improvements in weight status (grade B recommendation) (United States Preventive Services Task Force, 2010) and re-confirmed that recommendation in 2017. These recommendations were endorsed by the American Academy of Family Physicians (2014).

Several other health organizations have published recommendations for weight management in children and adolescents with overweight or obesity. The American Heart Association (AHA) in 2005 recommended five guiding principles for treating children who are overweight. These were: 1) establishing an age and comorbidity appropriate treatment plan, 2) involving the family, 3) frequent assessment and monitoring, 4) considering other behavioral, psychological, and social correlates, and 5) recommending change in diet and increase in physical activity within the family environment (Daniels et al., 2005). In 2013, the AHA recognized limitations of initial lifestyle modifications and pharmacotherapy for children and adolescents with severe obesity and recommended bariatric surgery as the most efficacious

treatment for severe obesity in adolescents (Kelly et al., 2013). The 2013 AHA recommendations were endorsed by The Obesity Society.

Also in 2013, two other organizations published their own statements. The Academy of Nutrition and Dietetics recommended comprehensive interventions for weight management in children and adolescents (Hoelscher, Kirk, Ritchie, & Cunningham-Sabo, 2013). The recommended interventions include the following components: 1) change in diet, 2) increase in physical activity, 3) behavioral counseling, and 4) parental/caregiver involvement. Active participation of parents/caregivers was deemed necessary for 2- to 5-year-old children along with monitoring of weight status. More intensive therapies, including pharmacotherapy or bariatric surgery were to be considered for children older than 6 years, after more intensive evaluation (Hoelscher et al., 2013). The National Institute for Health and Care Excellence (NICE) has recommendations for lifestyle weight management programs. Broadly, NICE (2013) recommended that all such programs be multicomponent and focused on diet and healthy eating habits, increase in physical activity and reduction in sedentary time, and behavior modification techniques in support of the children or adolescents, along with their families. Other earlier expert statements also focused on multicomponent interventions targeting diet, physical activity, sedentary behavior, and behavioral components in a family context. These include those published by the National Heart, Lung, and Blood Institute (NHLBI) Expert Panel (2011) and by the Endocrine Society (2008).

While the strength of the evidence in support of the recommendations proposed by these health organizations is variable, a common consensus is the requirement that interventions for the management of weight in children and adolescents with overweight or obesity include four key components. These components are: following a healthy diet, increasing physical activity and/or reducing sedentary time, incorporating behavioral practices in support of the required changes in behavior, and parental involvement. Involvement of parents or caretakers is considered important, particularly for young children.

The panel reviewed some existing systematic reviews that examined the efficacy of surgery for adolescents. While the panel did not conduct an exhaustive review of the literature in this domain, several reviews were identified. Three reviews examined reduction in weight or BMI outcomes (Ells et al., 2015; Paulus, DeVaan, Verdam, Bouvy, Ambergen, & Van Heurn, 2015; and Willcox & Brennan, 2014) while two reviews examined psychosocial outcomes of bariatric surgery (Herget, Rudolph, Hilbert, & Bluher, 2014 and Willcox & Brennan, 2014). The reviews did find that adolescents experienced substantial weight loss post-surgery with an "acceptable complication rate"[3] (Paulus, 2015, p. 860). Additionally, Herget et al. (2014) found that levels of depressive symptoms improved post-operatively and Willcox and Brennan (2014) found evidence for resolution of medical comorbidities but limited reporting of psychosocial outcomes. However, most reviews noted that surgery is typically considered only after attempts at lifestyle modification, consistent with recommendations from existing guidelines such as the recent document from the Endocrine Society (Styne, Arslanian, Connor, Farooqi, Murad, Silverstein, & Yanovski, 2017).

Methods and Process

Vetting and Appointment of Members to the Obesity GDP. The Advisory Steering Committee (ASC) put out a call for the nomination (including self-nomination) of both researchers and clinicians across various professional disciplines (psychology, social work, psychiatry, general medicine) who had content expertise in the topic area of obesity treatment as well as in biostatistics or methodology. The ASC sought those with knowledge of obesity

[3] Three surgeries were reviewed (laparascopic adjustable gastric band, Roux-en-Y gastric bypass, laparscopic sleeve gastrectomy) in a total of 37 studies. Perioperative complications occurred in 1-2% of surgeries. Up to 6% experienced infection at the surgical site. Depending on surgery, 5-10% of patients had gastrointestinal complaints (nausea, vomiting, GERD, diarrhea and gallstones) post surgery. Post LAGB, 14.7% had additional surgeries such as replacement, repositioning or removal of the band. Late complications, such as obstruction, ulcers and abdominal wall hernias, occurred in 20% of RYGB patients.

across age groups, sex, populations and treatment settings in order to seat a diverse panel with a variety of perspectives on obesity and its treatment that could discuss the research evidence and its applicability to those seeking treatment. Treatment developers who might have a strong allegiance to their particular method were not selected to serve on the guideline development panel (GDP) by the ASC, but their participation in the public comment period was encouraged. Additionally, community members, self-identified as having had obesity (currently or in the past), who were active in the leadership of groups that sought to enhance public awareness and access to services, were sought.

Conflicts of interest. Before final appointment to the GDP, nominees provided information regarding possible conflicts of interest, a significant issue in the AHRQ and IOM standards. *Conflicts of interest* (COI) are defined as, “a divergence between an individual’s private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual’s professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing” (Institute of Medicine, 2011; Schünemann et al., 2009). The IOM report additionally discusses intellectual COIs relevant to clinical practice guidelines, which are defined as “academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual’s judgment about a specific recommendation” (Institute of Medicine, 2011; Guyatt et al., 2010).

Candidates to the GDP each completed an APA COI form. Emphasis was placed on their disclosing all potential conflicts for the APA staff and ASC members to review and decide upon. While intellectual affiliations were expected, panel members were not to be singularly identified with particular interventions nor were they to have significant known financial conflicts that would compromise their ability (or appearance thereof) to weigh evidence fairly. It was understood however that some “adversarial collaboration” representing different points of view was to be expected and encouraged as part of the process. Upon successful completion of the

reviews, the ASC made the final membership recommendations to the APA Board of Directors for confirmation.

Once the panel was formed, all members completed an educational module on COI that underscored the importance of identifying and managing any COI that had either been identified or that might come to light. Members were asked to verbalize any actual or potential conflicts in their face-to-face meetings, so all members of the GDP would be familiar with the diversity of perspectives and range of possible influences and biases. COI forms were updated on an annual basis and panel members and staff were asked to provide more timely updates if there was any change in their disclosures that could be relevant to the development of an unbiased guideline. The APA COI policy and disclosure form can be found in Appendix B.

Scoping and Key Questions. The panel engaged in preliminary discussion of topic scoping at its first in-person meeting and then continued this discussion over a series of conference calls. The panel used a “PICOTS” (Population, Intervention, Comparator, Outcomes, Timing, and Setting) approach to scoping. With this approach, the panel used each of these elements as a framework to guide decisions about scope. Two tools were used to facilitate the scoping discussion: a review of existing guidelines and reviews on obesity identified by Kaiser Permanente Research Affiliates scientists and a survey that the panel used in order to rate the priority of various outcomes. Based on the existence of a recently released guideline focusing on treatment of obesity in adults (AHA/ACC/TOS, 2013), the panel decided to focus its work on children and adolescents. Based on the outcome prioritization survey in which panel members rated outcomes from 1 “not important” to 9 “critical” for making a decision about what treatment to recommend the panel decided to focus on BMI/ zBMI and serious adverse events as the most critical outcomes. Scoping decisions about which populations, interventions, comparators, outcomes, timing, and settings to include were as follows (O’Connor et al., 2016; p. A-17):

Category	Include	Exclude
Condition Definition	Studies identifying children [with] overweight or obesity according to sex- and age-specific criteria using methods such as BMI, BMI percentile, BMI z-score, or weight adjusted for height (percent ideal weight, percent overweight).	Studies using waist circumference, skin fold, bioimpedance, or other adiposity measures without also using age/sex-specific BMI measures.
Aim	Studies that include a weight reduction focus (primary aim may be targeting a comorbidity using weight reduction).	
Population	Age 2-18 years Either: (a) the entire sample has an age- and sex-specific BMI ≥ 85th percentile or meets other similar criteria for overweight based on ideal body weight, or (b) ≥ 50% of the sample has an age- and sex-specific BMI ≥ 85th percentile and ≥ 80% have risk factors for overweight (e.g., children of overweight parents; Hispanic, Black, or American Indian/Alaska Native ethnicity) or obesity-related medical problems (e.g., diabetes, metabolic syndrome, hypertension, lipid abnormalities, or other cardiovascular-related disorders).	• Average age < 2 years or > 18 years • …Youth who: (1) have an eating disorder, (2) are pregnant or postpartum, (3) [have] overweight or obesity secondary to a genetic or medical condition (e.g., polycystic ovarian syndrome, hypothyroidism, Cushing's Syndrome, growth hormone deficiency, insulinoma, hypothalamic disorders (e.g., Froelich's syndrome), Bardet-Biedl syndrome, Prader-Willi syndrome) or medication use (e.g., antipsychotics), (4) are in college

Category	Include	Exclude
Intervention	• Behavioral interventions that involve parents or caregivers in some way and include a minimum of 3 components: o Focus on increase in physical activity or decrease in sedentary behavior o Focus on dietary change o Behavioral component in support of 1 and/or 2 • May include complementary and alternative medicine approaches if 3 minimum components above are present • Intervention may target parents alone or in combination with the child • Mode of delivery must involve an interventionist and may include individual, group, family, multidisciplinary, internet, telephone, mailings, social media	• Primary prevention in normal weight children • Pharmacological interventions • Surgical interventions • Self-help intervention (must be interventionist) • Provides all or most of participants' food
Comparator	Any comparison of behaviorally-based components Agreed on 2-step approach. Efficacy studies were examined as a first step, followed by examination of only those comparative effectiveness studies that involve interventions that were found to be efficacious in the first step.	Active comparator if no efficacy established through review. [If the efficacy of an intervention could not be established first via the systematic review, it was not included as an active comparator (i.e., for comparative effectiveness).]
Outcomes	Studies must report BMI or weight adjusted for height or a similar measure (e.g. age- and sex-specific zBMI, BMI percentile, percent overweight)	Population changes in BMI or other adiposity measures in mixed primary prevention (normal weight) and populations that are overweight or have obesity.
Timing of Outcome Assessment	Outcomes assessed at or after 12 months post initial assessment and total duration of intervention.	
Setting	All outpatient settings (e.g., primary care, clinic, psychological services center, community, after school, virtual [technologically-delivered]).	Residential/Inpatient Classroom-based [These settings were excluded to meet constraints for the time and budget to complete systematic review.]
Study Design	[Randomized controlled trials] RCT, [Controlled clinical trials] CCT. [Trial that includes a control group comparison.]	All other study designs.

Category	Include	Exclude
Country	Economically developed countries, defined as OECD member countries: Australia, Austria, Belgium, Canada, Chile, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States.	Non-OECD member countries.
Publication Type	Peer-reviewed manuscripts and reports. (We tested for publication bias where there was an adequate number of studies for the statistical test or plotting approach.)	Non-peer-reviewed publications, book chapters, editorials, letters, non-systematic reviews, opinions, meeting abstracts
Language	English.	Languages other than English.
Publication Date	1985 – 2016 [Reflecting dates of earlier incorporated systematic reviews as well as updated bridge searches.]	
Study Quality	Fair or good, according to design-specific criteria.[4]	Poor, according to design-specific criteria.

Abbreviations: BMI = body mass index; CCT = clinical controlled trial; e.g. = for example; OECD = Organization of Economic Cooperation and Development; RCT = randomized controlled trial; USPSTF = U.S. Preventive Services Task Force

The five key questions identified by the panel were noted at the beginning of the document and in the key questions section below.

Comprehensive Search of the Professional Literature. As the name implies, a systematic review involves a methodical and organized search for studies and evidence of efficacy (and comparative effectiveness) regarding the treatment under consideration (Institute of Medicine, 2011b). The panel considered available systematic reviews and deemed no existing review met the criteria consistent with its key questions. Thus, the panel decided to commission a new systematic review, which was conducted by the Kaiser Permanente Research Affiliates EPC (O'Connor et al., 2016). For the systematic review, a variety of scientific databases were

[4] See Harris et al. 2001 for details regarding evaluation of study design and quality with particular emphasis on internal validity.

searched using selective search terms to identify relevant studies. The list of search terms is too extensive to include in this document but can be found in Appendix A (pp. A1 – A15) of the systematic review. The identified individual studies were then assessed to determine whether they met inclusion criteria (e.g., were ages 2-18) and rated, using pre-defined criteria, to establish quality. Studies were included if they met inclusion criteria and were randomized controlled trials (RCTs) or non-randomized controlled clinical trials (CCTs) that were of fair or good quality. Quality was rated based on criteria from the U.S. Preventive Services Task Force (USPSTF). Please see A17- A18 and page A19 in Appendix A of the systematic review for details of the inclusion/exclusion criteria and of the quality rating criteria respectively. A diagram on page A16 of Appendix A in the systematic review (O'Connor et al., 2016) shows the disposition of articles excluded and included in the systematic review. In brief, after an exhaustive search strategy, screening of 9,491 records, review by researchers of the full-text of 577 articles, 119 articles (65 studies [i.e., more than one published article resulted from some studies]) were included in the systematic review.

The Development of Evidence Tables. Evidence tables (summaries of data in available studies) were created by the Kaiser Permanente scientists from evidence collected for the systematic review regarding the efficacy or comparative effectiveness of treatments. These tables contain the foundational evidence on which current recommendations were made and generated some of the information included in the Grid (described below). The evidence tables (please see Appendix D of the Kaiser Systematic Review (O'Connor, et al., 2016)) were abstracts of data included in the systematic review and include, as available for each body of evidence, the number of studies, effect sizes, confidence intervals (when available) and quality ratings.

The Development and Use of the Grid. The Grid was a document developed and used by panel members to summarize and evaluate the evidence generated in the systematic review, along with any supplemental information. Panel ratings and judgments were documented on the

Grid to assist in the formulation of recommendations. This Grid allowed panel members to document decisions, compare consistency across decisions, and provide transparency to reviewers and users of the guideline document. Decisions were documented in four main domains: 1) strength of evidence; 2) the balance of benefits vs. harms/ burdens of interventions; 3) patient values and preferences; and, 4) applicability of the evidence to various treatment populations. The Grid (http://apacustomout.apa.org/commentPracGuidelines/Practice/Grid%20for%20Obesity%20GDP%20Recommendations%20for%20posting.pdf) was comprised of distinct columns for separate key questions to allow decision-making by key question. However, it was formatted to allow consideration of the same data for harms and burdens across those columns/key questions.

Although some have questioned the applicability of some randomized trials due to potential differences between sample characteristics or treatment settings and the "real world," the panel decided to not supplement the randomized trials included in the systematic reviews (SRs) with observational (i.e., non-randomized and less methodological rigorous) treatment studies, due to the potential for confounding bias in observational studies (Fewell, Smith, & Sterne, 2007; Rothman, Greenland, & Lash, 2008). This decision is consistent with the position of all major organizations that evaluate research and conduct systematic reviews, including GRADE, Cochrane, NICE, AHRQ Evidence-Based Practice Centers, that randomized trials have lower potential for bias than observational studies (Guyatt et al., 2011; National Institute for Health and Care Excellence, 2012; Reeves et al., 2011; Viswanathan et al., 2012).

Panel members made two significant exceptions to this decision when it became clear that data were lacking in randomized trials regarding two outcomes: 1) harms and burdens of psychosocial treatments, and 2) patient values and preferences with regard to particular treatments. In response, the panel determined there was a need to gather and review additional information on these topics. Concerning harms, panel members decided to review those observational studies that gave attention to the assessment of harms that were identified in the

systematic reviews. It also authorized APA staff assigned to the GDP to compile information on possible harms and burdens of interventions as well as patient values and preferences from an additional review of the literature. Concerning patient values and preferences, the panel considered data from the search of the literature conducted by APA staff and information from consumer and clinician members of the panel. Details of the search process methodology for both of these supplemental sources of information are described below. The findings of these additional reviews along with input from clinicians and consumers on the panel were used to make the treatment recommendations more comprehensive with regard to the risk of harm or adverse events associated with treatment for overweight or obesity, and patient values and preferences.

Each panel member was given an explicit opportunity to raise any questions or concerns about how the Grid was completed. The panel reviewed the Grid to identify any questions or concerns that audiences of the guideline (including patients, clinicians, and scientists) might raise. For purposes of consistency across all CPG, the ASC established voting procedures that can be found in Appendix C.

These four domains of information (overall strength of the evidence, balance of benefits vs. harms, patient values and preferences, and applicability) constituted the basis on which each treatment recommendation and its strength was determined. For each recommendation, text description and a justification for the recommendation were included on the Grid.

Rating of Aggregate/Global Strength of Evidence (SOE). For each column of the Grid (which corresponds to a question of interest), aggregate/global SOE was based on the SOE from the systematic review for the two critical outcomes; namely, response to treatment (measured as BMI/zBMI) and serious adverse events. In accordance with the GRADE consortium system, the panel adhered to the rule that the aggregate SOE could be no higher than the lowest individual SOE for each of the critical outcomes *(*Guyatt et al 2013*).* For example, if one critical outcome had ‘high’ strength of evidence but the other critical outcome

had ‘low’ strength of evidence, the global quality of evidence for that particular column in the Grid would be ‘low,’ since that is the lowest SOE for an individual critical outcome. The strength of evidence for serious adverse events, one of the panel’s critical outcomes, was insufficient/very low, for all interventions for which Grid columns were completed. This explains why the global strength of evidence was insufficient/very low for all interventions, despite low, moderate or high strength of evidence for the critical outcome of BMI/zBMI. Thus, the application of the rule of aggregate strength of evidence is a limitation in the case of behavioral interventions where the harms are considered minimal. The panel rated each component separately to highlight the higher strength of evidence for BMI/zBMI.

Assessing Magnitude of Benefits. One of the key components of the decision-making process for the GDP was assessment of the balance between benefits and harms. This required that both benefits and harms be quantified. This section describes the methods used to quantify the magnitude (size) of benefits.

Quantification of benefits was based on data from the quantitative meta-analyses for each column of the Grid. Magnitude of benefits was rated as large, medium, or small benefit of treatment or no difference in effect or unable to rate.

Assessing Magnitude of Harms/Burdens. Since “serious adverse events” was one of the two critical outcomes of treatment decided upon by the panel, these needed more precise specification and definition. Ultimately, panel members defined events such as medical problems (e.g., stunted growth) as a serious adverse event. Harms were differentiated from burdens with harms being negative events resulting from treatment (e.g., symptom worsening) and burdens were identified as disruptions associated with treatment (e.g., time spent, convenience). As discussed earlier, the systematic review of the treatment literature did not generate sufficient data on harms and burdens of interventions because this information is not routinely reported in studies.

In response to this deficit, the panel commissioned APA staff to examine articles in the systematic review to extract data regarding harms and burdens, such as dropout/attrition, symptom worsening, etc. All included trials were reviewed for harms and burdens. Four hundred fifty-eight excluded articles are listed in Appendix B. To reduce this number and to be consistent with methodology utilized with previous CPG panels, excluded articles that were either: (1) not an RCT/CCT and (2) reported high dropout and attrition OR had some other quality issue or not enough information to assess quality were identified, resulting in 93 articles (all other excluded articles did not satisfy other inclusion criteria such as type of intervention, population, etc.). Forty-one of these 93 articles were freely accessible on the internet or through existing library resources (no requests were made to the librarian to locate full text of missing articles). Twenty-five of the studies provided usable data. The other 16 articles included commentaries, study protocols, or secondary analyses of primary trials and as such were not included in analyses of harms and burdens. Information regarding harms and burdens contained in these excluded studies was examined because doing so is acceptable under the IOM standards, which allow more relaxed criteria when examining literature on harms/burdens (Institute of Medicine, 2011b, p. 8). No additional literature searches were conducted.

It was from these studies that the panel had additional information on possible harms or burdens associated with the interventions under consideration. All of this evidence was rated insufficient/very low strength of evidence due to inclusion of observational study designs, which have a higher risk of bias than randomized trials.

Finally, to supplement the limited information on harms and burdens gleaned from published research, clinicians on the panel reported their experiences in delivering, supervising or training in particular interventions and the concerns noted by colleagues. The community member reported on both her own and peer experiences with various interventions. Though it was important to obtain all available sources of information on harms and burdens, due to the inclusion of both anecdotal (i.e., clinician and community member report) and peer reviewed

article information, the Strength of Evidence on these topics was considered insufficient/very low. Magnitude of harms/burdens was rated as large, medium, small, or no harm/burden of treatment or unable to rate.

Once possible harms and burdens were identified, panel members then compared these with the benefits of the interventions. On the Grid, the panel rated whether the balance of benefits to harms/burdens strongly or slightly favors Treatment 1 over Treatment 2/control or the reverse, if the balance of benefits to harms/burdens was the same, or if the panel was unable to determine the balance of benefits to harms/burdens between Treatment 1 and Treatment 2/control.

Assessing Patient Values and Preferences. In addition to assessing the benefits and the harms/burdens associated with specific interventions, the panel attempted to ascertain patient values and preferences. As described above, to ascertain this information, the panel relied on a search of the literature as well as clinicians and consumers on the panel who voiced their perspectives about preferences for different interventions as well as the value that patients might place on different outcomes or harms/burdens associated with particular treatments. The SOE for all of this information was very low because it included observational studies and "expert" (i.e., panel member) opinion.

Applicability of Evidence. The final determinant that panel members considered, before making recommendations, was the applicability (generalizability) of the evidence to various populations and settings. To organize information on applicability, panel members applied the PICOTS framework (referring to Populations, Interventions, Comparators, Outcomes, Time and Settings; Samson & Schoelles, 2012). The panel reviewed specific information from the studies to determine if there were any concerns pertinent to applicability pertaining to population, interventions, comparators, outcomes, timing, or settings needed to be included and noted on the Grid.

Decision-Making Regarding Treatment Recommendations. On the basis of the ratings of these four factors (strength of evidence, balance of benefits versus harms/burdens, patient values and preferences, and applicability) the panel then made a decision regarding its recommendation for a particular treatment or comparison of treatments. The options included a strong ("the panel recommends") or conditional ("the panel suggests") recommendation either in support of or against a particular treatment on the basis of the combination of these factors. Panel members could also decide that there was insufficient evidence to be able to make a recommendation about a particular treatment. Panel members were able to reach consensus regarding the strength of each recommendation.

External Review Process. This document was submitted to the ASC for feedback. The ASC comments were given a detailed review and response, and the document was modified based on that feedback. The document is currently posted on the APA web site and public feedback is solicited for 60 days. The document will be revised based on that feedback. Detailed responses to public comments will be made available upon request.

Recommendations and Statement of Evidence

Of the 65 included trials, 36 were "efficacy trials" that evaluated the family-based multicomponent behavioral intervention against a control group. Two trials were maintenance only interventions ("maintenance trials") that participants engaged in after finishing the weight reduction intervention. Thirty-four of the trials were classified as "comparative effectiveness" due to including at least two active intervention arms. However, six of these were also classified as efficacy trials due to including a control group. See Table 2 for details of effect sizes.

Recommendation:

For child and adolescent patients with overweight or obesity, the panel strongly recommends the provision of family-based multicomponent behavioral interventions, with a minimum of 26 contact hours, initiated at the earliest age possible.

Statement of evidence rationale:

- Out of 36 efficacy trials for children or adolescents with overweight or obesity, family-based multicomponent behavioral interventions showed an average reduction of -0.16 zBMI (95% confidence interval: -0.24 to -0.07) relative to non-active controls.
- Out of 40 efficacy and comparative effectiveness trials for children or adolescents with overweight or obesity, family-based multicomponent behavioral interventions achieved a zBMI reduction greater than or equal to -0.25 in 37.5% of the trials. These 40 efficacy and comparative effectiveness trials provided moderate quality evidence of a small effect.
- Two trials provided low quality evidence of no maintenance effect.
- Out of 12 efficacy trials for children or adolescents with overweight or obesity, family-based multicomponent behavioral interventions with 26 or more contact hours showed an average reduction of -.27 zBMI (95% confidence interval -0.38- -.16) relative to non-active controls.
- Out of 24 efficacy and comparative effectiveness trials for children or adolescents with overweight or obesity, family-based multicomponent behavioral interventions with 26 or more contact hours achieved a zBMI reduction greater than or equal to -0.25 in 58.3% of the trials. These 20 efficacy trials provided moderate quality and these 4 comparative effectiveness trials provided low quality evidence of a medium effect.

- Out of 13 efficacy trials for children or adolescents with overweight or obesity, family-based multicomponent behavioral interventions with less than 26 contact hours showed an average reduction in zBMI of -0.04 (95% CI -0.10 to 0.01).
- Out of 16 efficacy and comparative effectiveness trials for children or adolescents with overweight or obesity, family-based multicomponent behavioral interventions with less than 26 contact hours, only one trial achieved a zBMI reduction greater than or equal to -0.25, which was 6.2% of the trials. These trials provided moderate quality evidence of no effect.
- Out of 25 efficacy or comparative effectiveness trials for children or adolescents with overweight or obesity using family based multicomponent behavioral interventions with 26 or more hours of contact, there was a significant association ($p = 0.03$) between age and whether the trial met the clinically significant reduction in zBMI greater than 0.25.
- Among the 14 trials showing a clinically significant reduction, 10 (71%) targeted preschool or elementary aged children. All trials targeting preschool children showed a benefit.
- Of the trials that did not show a benefit, 3 (27%) targeted elementary school age children, and 4 (36%) targeted adolescents. These trials provided low quality evidence that the effect is stronger when intervening with young children.
- Beyond the number of contact hours, neither the number of sessions or the length of treatment was related to efficacy of treatment.
- There was no evidence that *other* selected characteristics of family-based multicomponent behavioral interventions, including setting, interventionist qualifications, mode of delivery, use of multidisciplinary team including involvement of a psychologist, or cultural tailoring, had independent effects on zBMI.

Recommendation:

There was no association to suggest severity of adiposity, parental obesity, race or ethnicity, and insufficient evidence to suggest socioeconomic status made a difference in the outcome of high intensity family based multicomponent behavioral interventions.

Statement of evidence rationale:

- Out of 36 efficacy trials for children or adolescents with overweight or obesity using family based multicomponent behavioral interventions with 26 or more hours of contact, the following characteristics: child's age categorized as preschool (age 2 to 6 years), elementary (ages 6 to 12 years), or adolescent (age 12 to 18 years); target children who are overweight; required at least one parent to have overweight or obesity; or 50% or more Black or Hispanic, showed nonsignificant effect modification on zBMI (ps 0.22 to 0.98) in meta-regression. These trials provided low quality evidence of no effect modification.
- Evidence was insufficient to evaluate socioeconomic status, as only 2 efficacy trials targeted participants of low socioeconomic status.
- There was a significant association ($p = 0.03$) between race/ethnicity and whether the trial met the clinically significant reduction in zBMI greater than 0.25. None of the four trials with 50% or more of black and Latino children met criterion for clinical significance. However, none of these four trials targeted young children. Thus, the effect modification associated with race/ethnicity was confounded with age.

Recommendation:

There was insufficient evidence to determine the comparative effectiveness of selected strategies of family based multicomponent behavioral interventions including goals and planning, comparison of outcomes, self-monitoring of behavior, self-monitoring of

outcome, contingent reward or threat, stimulus control, modeling of healthy lifestyle behaviors by parents, motivational interviewing, or parenting skills training. Therefore, practitioners have a fair amount of flexibility in selecting an efficacious family-based multicomponent behavioral intervention program of sufficient intensity that addresses physical activity, nutrition, and behavior change with strategies used to accomplish change appropriate for particular patients and local implementation needs.

Statement of evidence rationale:

- Out of 14 efficacy trials for children or adolescents with overweight or obesity, family based multicomponent behavioral interventions with 26 or more contact hours and clinically significant effects of ≥ -0.25 zBMI included behavioral intervention components including goals and planning, behavioral self-monitoring, contingent reward or threat, stimulus control, parental modeling, or parental skills training in at least 70% of these trials. These 14 trials provide low quality evidence of no effect for any one single intervention strategy. [Based on low quality evidence rating for goals/planning, very low for types of goals, low for collaborative goals, low for parent modeling and skill training, low for other components.]
- Based on no comparative effectiveness trials for comparison of outcomes, motivational interviewing, self-monitoring of behavior and outcome, contingent reward or threat, stimulus control, and parental modeling.
- Nonsignificant results from meta-regression analyses for goals/planning, collaborative goals, parent modeling and parenting skills training.
- Only 3 contradictory comparative effectiveness trials for parenting skills and also confounded by age of children where this technique was used most often; low quality evidence.

Recommendation:

There was insufficient evidence to determine whether specific intervention characteristics or strategies were associated with patient adherence (other than attendance), engagement, or retention. Higher attendance was associated with greater efficacy but there was insufficient evidence to determine whether patient adherence (beyond attendance) was associated with efficacy.

Statement of evidence rationale:

- No intervention strategy or characteristic was associated with patient adherence.
- Patient adherence was not consistently defined or reported across studies.

Table 2: Summary of considered intervention components and association with effect size

Intervention Strategy	**Effect size** Regression coefficient† (95% CI)
Goals and planning*	-0.32 (-0.74 to 0.13)
Collaborative goals	0.15 (-0.07 to 0.37)
Motivational interviewing	-0.03 (-0.23 to 0.29)
Self-monitoring behavior	-0.04 (-0.26 to 0.18)
Self-monitoring of weight	-0.15 (-0.44 to 0.15)
Contingent reward or threat	-0.15 (-0.38 to 0.07)
Stimulus control	0.07 (-0.16 to 0.30)
Parental modeling	-0.08 (-0.30 to 0.15)
Parenting skills training	0.08 (-0.16 to 0.33)
Comparison of outcomes	0.20 (-0.03 to 0.43)
Intervention Characteristics	
Contact hours	-0.01 (-0.01 to -0.01)
Number of sessions[5]	-0.01 (-0.02 to -0.01)
High (≥26) contact hours	-0.43 (-0.68 to -0.18)
Duration	-0.01 (-0.03 to 0.01)
Provider Qualifications	

[5] While the results for contact hours and number of sessions were significant, the panel determined that the magnitude was so small as to be close to 0. Only when dichotomizing the number of contact hours into high and low did the size of the effect appear meaningful.

Interventionist who provided the behavioral component was a behavioral specialist	-0.28 (-0.56 to 0.01)
Psychologist on team	-0.17 (-0.44 to 0.10)
Interventionist who provided the dietary component was a dietary specialist	0.04 (-0.25 to 0.33)
Interventionist who provided the physical activity component was a physical activity specialist	0.13 (-0.18 to 0.45)
Multidisciplinary team	0.16 (-0.09 to 0.42)
Setting	
Primary care	-0.02 (-0.28 to 0.25)
Other health care	-0.10 (-0.36 to 0.16)
Non-health care/community	0.12 (-0.14 to 0.37)
Delivery Format	
Offered group sessions	0.30 (-0.00 to 0.61)
Offered individual (single-family) sessions	-0.34 (-0.67 to -0.00)
Offered individual (single-family) sessions, among trials that also provided group sessions	-0.34 (-0.73 to 0.05)
Offered sessions targeting family all together	-0.01 (-0.27 to 0.24)
Offered sessions targeting child only (without parent)	-0.02 (-0.31 to 0.26)
Offered sessions targeting parent only (without child)	-0.03 (-0.31 to 0.24)
Included an electronic delivery component	-0.20 (-0.53 to 0.13)
Included a print-based delivery component	0.07 (-0.16 to 0.30)
Included a phone-based delivery component	0.11 (-0.12 to 0.34)
Included supervised physical activity sessions	0.27 (-0.06 to 0.60)
Included supervised physical activity sessions, among interventions offering ≥26 contact hours	0.16 (-0.59 to 0.92)
Cultural Tailoring	Insufficient evidence

*Almost all trials featured this strategy so insufficient variability to yield valid meta-regression results

Potential Harms and Burdens of Treatment

Potential Harms

No medical harms for the recommended treatment were reported in studies and several specifically indicated the following potential medical concerns did not occur: impaired height or linear growth (Golan, Kaufman, & Shahar, 2006; Golley et al., 2007; Hughes et al., 2008;

Raynor et al., 2012; Savoye et al., 2007), development of injury or allergy (Raynor et al., 2012), impaired child-health status (McCallum et al., 2007, Wake et al., 2009; Wake et al., 2013), or increase in eating pathology (Epstein, Paluch, Saelens, Ernst, & Wilfley, 2001).

The panel recognizes that family conflict could arise during treatment. Children could develop psychological issues related to the success or failure of the recommended intervention. Few studies assessed psychological well-being but 11 did report on quality of life and only one study suggested a possible negative impact from the intervention; all others reported no difference or suggested the higher intensity intervention may result in slightly improved quality of life.

Potential Burdens

The panel noted potential burdens, such as extra effort needed to access treatment (recommended treatment is more often available in specialty clinics but specialty clinics are not in every geographical area and not always easily accessed), and lack of access to safe physical activity and healthy foods. Another potential burden is that treatment does require at least two family members, a parent and a child, to be engaged. Not all families may have two family members ready to engage in the recommended intervention. Another potential burden is the amount of time required (both meeting with providers and at home); the hours can be inconvenient and be difficult and costly if parents have to take time off from work, the child can suffer academically if needing to be repeatedly taken out of school, and transportation can be a challenge. While there is a relationship between an increasing number of the burdens and increased contact intensity of the recommended intervention, the panel did not observe a difference in drop out rate between low- and high-intensity interventions.

The panel suggests that providers should address perceived burdens during intervention. Further, potential burdens may be moderated by the socioeconomic status of the family, with families of lower socioeconomic status perceiving potential burdens as larger barriers to participating in the recommended treatment. Note however that these data were not

systematically analyzed- they come mostly from anecdotal reports from clinicians and community members and from public health reports regarding access to food and activity.

Implementation

The primary focus of this guideline is to provide evidence-based recommendations for interventions used in the treatment of childhood obesity. Based on the synthesis of the literature, this section will highlight program components and potential barriers and strategies to be considered for successful program implementation. Five things in particular should be considered for successful implementation:

First, it is unknown if all of the strategies of successful trials noted above are necessary or how each affect individual outcomes. There was no direct evidence to support a specific strategy or mode of delivery of dietary intervention or physical activity regimen over another. Thus, until further research compares strategies directly, practitioners have a fair amount of flexibility when choosing specific elements or mode of delivery within the areas of physical activity, nutrition, and behavioral change when implementing or developing new programs. The panel recommends utilizing all the strategies employed in one of the studied, efficacious intervention programs when offering care.

Second, flexibility in treatment setting together with problem solving is needed to address location and other practical concerns that are potential barriers to treatment. Since there was insufficient evidence to recommend a specific program venue, offering care in the variety of settings available in rural and urban areas, such as schools, medical settings, community centers and faith-based settings, is important to increase accessibility. Additional concerns include program cost and waitlists. During program development, other barriers to attendance (e.g. scheduling, transportation, and childcare) should be anticipated with potential solutions made available to the family.

The third implementation consideration relates to the age of the child. Evidence suggests treatment may work especially well for young children, supporting the importance of intervening as early as possible. Very few trials targeted adolescents and the trials that did failed to meet clinical significance. Specifically, only three trials targeted adolescents exclusively (ages 12 and up) whereas six trials targeted ages six and younger, 17 trials targeted ages 6-12, and the remaining 10 trials spanned multiple age ranges. However, due to the limited studies targeting adolescents, the increased risk for the obesity to carry over into adulthood, and the subsequent risk of the development of weight-related comorbidities, it is recommended that further research be conducted on this high-risk age group. It would be particularly important to determine whether alternative treatments may be more efficacious among adolescents. As programs are developed for each of the age groups, the child's developmental age as well as the participants' culture, values and preferences should be integrated into the interventions (i.e., see Falbe, Cadiz, Tantoco, Thompson, & Madsen, 2015; and Hammons, Wiley, Fiese, & Teran-Garcia, 2013). Addressing these issues will support respect for the family and participant engagement in the program.

The fourth implementation consideration pertains to the need for practitioners to develop knowledge, skills, and awareness related to weight bias and stigma (differential and negative treatment and attitudes experienced by people who have overweight or obesity). Health professionals and family members have been identified as the most frequent sources of weight stigma for individuals with obesity (Puhl & Brownell, 2006; Puhl & Latner, 2007; Puhl, et al., 2013). Weight stigma has a negative effect on weight management. An increased exposure to weight stigma is associated with higher BMI and controlled research has found increased cortisol and caloric consumption in adult women following stigmatization (Schvey, et al., 2011; Schvey, Puhl, & Brownell, 2014). Consequences of weight stigma reported in children include psychosocial concerns of lower self-esteem, depression, body dissatisfaction, and a negative impact on their interpersonal relationships (Puhl & Latner, 2007). Thus, in the panel's expert

opinion, it is critical that providers implementing the intervention be educated about weight bias and stigma, and develop awareness and skills to interact with children and families in a nonjudgmental and empowering manner. Furthermore, the panel encourages providers to work with children and parents to address stigma that may be occurring within the family (e.g. name-calling, shaming, and criticism related to weight). Individuals may want to be familiar with the Provider Competencies for the Prevention and Management of Obesity (Robert Wood Johnson Foundation, 2017).

Fifth and finally, these are multicomponent interventions, often delivered by multidisciplinary teams. These interventions can be delivered in specialty clinics as well as integrated care settings but consensus suggests that providing treatment for obesity within integrated systems of care is preferred (Wilfley et al., 2016). Integrated care that includes both physical and behavioral health experts has been shown to provide many benefits to patients through improved adherence to treatment recommendations, decrease in hospitalizations and improvements in patient outcomes (American Psychological Association, 2016). The care delivery team for the treatment of children with overweight and obesity typically consists of a primary provider tasked with medical oversight along with a behavioral health care provider specifically trained in the management of childhood obesity. Additional team members may include physical activity specialists and dietitians. Team members need to possess skills in working across disciplines, communicating, and working collaboratively with other providers and the patient and family to accomplish shared goals.

Discussion

Applicability of Results and Clinical Significance

The trials included in our review spanned a range of ages, settings, recruitment methods, and types of professionals delivering the intervention. There was insufficient evidence to conclude that type of setting or provider has an effect on outcome of the child's BMI. It should

be noted that high intensity intervention studies were more likely to report that providers had expertise in behavior change, diet and physical activity. Multiprofessional competencies for providers of care for individuals with overweight and obesity include not only appropriate discipline expertise (such as knowledge of diet and nutrition or knowledge of principles of behavior change) but also knowledge and skills specific to the physiology of overweight and obesity, interprofessional team work and other areas (Robert Wood Johnson Foundation, 2017).

There is some concern, however, about the applicability of results for certain populations, including groups most affected by obesity. Race and ethnicity were not reported in many trials, and there were relatively few trials that included at least 50% black or Hispanic youth, who are disproportionately affected by obesity. Trials including a significant number of Latino or African American participants were more likely to include interventions that were culturally tailored, had supervised physical activity, and occurred in non-health care settings. However, due to the poor overall quality of the data these findings were not able to be considered in drafting recommendations.

The panel was also not able to answer questions related to socioeconomic status due to limited data, and very few trials specifically targeted participants of low socioeconomic status. Regarding age, there is some evidence that family-based interventions geared toward younger children are more likely to meet clinical significance. None of the trials targeting adolescents met the threshold for clinical significance; thus, there is some question of applicability of the recommendation for this population. Adolescents with obesity represent a population at high risk for adult obesity and obesity-related comorbidities, it is critical that attention be given to finding appropriate and effective interventions for them.

Additionally, studies with youth who have an eating disorder, were pregnant or postpartum, or have overweight or obesity secondary to a genetic or medical condition were not included in the review. While these youth also could potentially benefit from family-based, multicomponent behavioral interventions, modifications may be needed with these populations

and this is an important area for further research. Children and adolescents with eating disorders, for instance, may have problematic eating patterns or beliefs about food that will need to be addressed along with supportive changes to diet. Those females who are pregnant or postpartum or have a genetic or medical condition may have specific dietary or other health care needs that must be addressed along with the implementation of the behavioral intervention.

The panel only examined BMI/zBMI as an outcome as that was the only outcome consistently captured across studies; therefore, while interventions may have impacted other outcomes including health behaviors (e.g. food choices, amount of exercise), other anthropometric variables besides BMI, and/or psychosocial variables, any of which could affect weight status over time, it would not be captured in this document. Thus, recommendations could shift or be refined as more data become available for other indicators of behavior change or health status. However, the lifestyle focus of the intervention results in improvements in eating habits and activity levels which in and of themselves can have important benefits, independent of changes in BMI/zBMI. Further, the level of obesity in the children represented in these trials tended to be quite high. Across all 36 efficacy trials, the average baseline zBMI was 2.1 (weighted by the trials' sample sizes), which is well above the zBMI for the 95th percentile of 1.645. The panel does not know if or how its recommendations apply for children closer to the 95th percentile.

Consideration of Patient Values and Preferences

The panel supported adoption of the 26 contact hour recommendation as a necessary minimum treatment level. For many children and families, more contact hours, including ongoing support, will be necessary to have an impact on weight trajectory. Thus, the panel believes the guideline recommendations are a minimum first-step towards addressing and treating childhood obesity.

While supporting the overall guideline, the panel noted several challenges surrounding its implementation. First, not all parents recognize that their child has overweight or obesity, or know the long-term health consequences associated with it. This can be due to a variety of factors, including insufficient understanding of the conditions and differing cultural values surrounding weight. The panel supported encouraging awareness of this issue, especially among health care providers who are in a position to monitor a child's weight trajectory, objectively identify overweight or obesity status and recommend treatment.

Second, handling the logistics of a family-based, time-intensive treatment program could be problematic for many families. Competing time issues with work and school could prevent successful participation in an adequate treatment program. Other logistical issues, such as childcare for young children and transportation to the treatment location, could create other barriers. These barriers are likely to be higher for lower-income families. The panel urges providers to consider these logistical problems when creating treatment programs. For instance, time-sensitive scheduling, such as offering treatment during evening and weekend hours, could alleviate some of these problems.

Third, obtaining 26 or more contact hours may be cost-prohibitive for many, if not most families. Insurance coverage for treatment of obesity varies such that behavioral counseling by a primary care provider for adults is typically covered but the treatment is not intensive nor provided by specialists and coverage for children and adolescents is more variable, particularly within the Medicaid system. Most coverage does not include participation in intensive multicomponent treatment, weight management programs or nutritional counseling. Similar to logistical issues, cost issues will likely have a larger negative impact on low-income families. See Wilfley, Staiano, & Altman, et al. (2017) for further discussion on this topic. The panel urges providers, professional associations, and patient advocacy organizations to continue to work with insurance companies and government policy-makers to advance coverage for obesity prevention and treatments generally, and for children in particular.

Finally, the panel stressed the importance of treating children with overweight or obesity—as well as their parents or guardians—in a non-judgmental, non-stigmatizing manner. As noted, these children are already subjected to weight-based bullying and increased stigma. Adverse childhood experiences, such as abuse or exposure to violence, can also contribute to weight gain and should be considered. Furthermore, children may be singled out by their peers or other family members simply because they seek treatment or participate in a weight-management program. In addition, parents and guardians may also suffer from overweight or obesity and either be blamed or perceive being blamed for their child's weight condition. Providers need to be sensitive to these issues and the impact they have on the child's self-esteem and the willingness of the child and family to participate in treatment. The panel strongly recommends that providers be educated about the genetic, biological, psychological, social, and environmental complexities associated with obesity. This knowledge will allow the provider to have a fuller understanding of the condition, grasp the challenges their patients with overweight or obesity face, appreciate the difficulties parents and guardians encounter in helping the child manage weight, which will improve their ability to treat their patients.

How this Guideline Compares to Other Guidelines for Treatment of Children and Adolescents with Obesity

The broad conclusion reported in this guideline, that for children or adolescents with overweight or obesity, family-based multicomponent behavioral interventions have a small effect, based upon trials providing moderate quality evidence, is similar to the conclusions the 2008 expert committee (Spear et al., 2007), the US Preventive Services Task Force (2010, 2017), and several other health organizations (Hoelscher et al., 2013; Daniels et al., 2005; Fitch et al., 2013; NICE, 2013; August et al., 2008; American Association of Clinical Endocrinologists and American College of Endocrinology,1998; National Health and Medical Research Council, 2013; National Heart, Lung, and Blood Institute, 2011; Scottish Intercollegiate Guidelines

Network, 2010; Working Group of the Guideline for the Prevention and Treatment of Childhood and Juvenile Obesity, 2009). The findings of the importance of intensity of contact time, with family-based multicomponent behavioral interventions with 26 or more contact hours providing moderate to low quality evidence of a medium effect, and those with less than 26 contact hours providing moderate quality evidence of no effect, is similar to the findings, both in terms of the quality of the evidence and the size of the intervention effect, of the systematic review conducted in 2010 for the USPSTF recommendations (Whitlock et al., 2010). Furthermore, the recommendation that family-based multicomponent behavioral interventions for children and adolescents with overweight or obesity have at least 26 contact hours is similar to both the 2010 and 2017 USPSTF recommendation. The predominant difference between the recommendations is that the USPSTF recommendation is for children aged 6 to 18 years, while the recommendation from this guideline includes the age range of the systematic review, 2 to 18 years, with particular note of the effectiveness of intervention with preschool and elementary age children diagnosed with overweight or having obesity.

Other conclusions of this effort, including insufficient or low-quality evidence on effect moderators and components of the intervention and patient engagement factors that most strongly influence outcomes, reflect the lack of research conducted in this area. The need for additional research in childhood weight intervention to strengthen recommendations has been identified previously (Spear et al., 2007; Whitlock et al., 2010). The conclusion that there was insufficient evidence that setting, interventionist qualifications, mode of delivery, use of multidisciplinary team including involvement of a psychologist, or cultural tailoring, had independent effects on zBMI is new to this effort.

Limitations of Existing Treatment Research Literature: Future Research Needs

In the systematic review, several limitations were identified, suggesting areas that require additional research to strengthen the ability to develop practice guidelines for the

treatment of childhood overweight and obesity. One limitation is the lack of guidance regarding the amount of reduction in adiposity needed to improve other aspects of health, particularly cardiometabolic health, in children and adolescents. In adults, a reduction of 3-5% of weight produces clinically relevant health benefits, such as reductions in triglycerides, blood glucose, and hemoglobin A1C, and greater amounts of weight loss produce greater benefits, particularly in regards to blood lipids (decreases in low-density lipoprotein cholesterol and increases in high-density lipoprotein cholesterol) (Jensen et al., 2013). Unfortunately, in children and adolescents, the degree of reduction in adiposity that is required to produce clinically relevant health benefits has not been identified (Coppock, Ridolfi, Hayes, St. Paul, & Wilfley, 2014) although reduction in BMI is associated with improvements in metabolic outcomes (Styne et al., 2017). Some studies do suggest that the cut-off used in this guideline, a reduction of $\geq$ 0.25 zBMI, can improve cardiovascular risk factors in children and adolescents (Ford, Hunt, Cooper, & Shield, 2010; Kolsgaard, Joner, Brunborg, Anderssen,Tonstad, & Andersen 2012). However, more research is needed to establish, similarly to that which has been achieved with adults, the minimal amount of reduction in zBMI needed to achieve clinically relevant health improvements in children and adolescents. Identifying the minimal effect needed will assist in evaluating treatment options for children and adolescents with overweight or obesity. Additionally, the systematic review only focused on the outcome of adiposity, as evidenced by BMI. The multi-component interventions may have additional benefits, including improvements in diet quality, physical activity, and psychosocial outcomes, which were not reviewed but would be important on their own.

It is important to develop clinical practice guidelines that can address the noted health disparities in childhood obesity. Although it was determined that trials that included a significant number of African American or Latino participants were more likely to include culturally tailored interventions, supervised physical activity, and take place in non-health care settings, these

findings could not be considered in the recommendations due to the overall poor quality of the data. Additionally, it is worthwhile to note that in many cases, race and ethnicity were not reported in the participant section of the published reports. To address the significant health disparities that do exist in childhood obesity it is imperative that researchers report the race and ethnicity of their participants, consider how culturally tailored interventions may increase treatment efficacy, and describe in detail how interventions are tailored (Seo & Sa, 2010). Please see Table 3 for a list of future research considerations.

Similarly, there was insufficient evidence to explore the role that socioeconomic status played in treatment efficacy. Again, there were a low number of studies that reported the socioeconomic background of families participating in treatment programs and none that targeted participants of low socioeconomic status. Given the disproportionate prevalence of obesity in low-income households (Ogden et al., 2012), it is incumbent upon researchers to accurately report the socioeconomic background of participants and design studies that target families of low socioeconomic status such that more effective means of treatment may be developed for vulnerable families. Further, researchers designing trials targeting these vulnerable families will need to address issues of access to food (Baker, Schootman, Barnidge, & Kelly, 2006) and safe physical activity (Evans, 2004).

For the key questions in the review about the impact of selected strategies of family-based behavioral management interventions in the management of age/sex zBMI and the effect of patient adherence, engagement, and retention, it was determined that there was insufficient evidence. Lack of detail in methodology and/or results prevented the ability to code components of the program and determine adherence and engagement. To assist with understanding these factors on treatment outcomes, researchers are encouraged to provide more detail in these areas. For example, intervention strategy implementation should be described (i.e., how the strategy was conceptualized in the intervention, when and to whom the strategy was introduced, and length of implementation during intervention), and participant adherence to intervention

strategy implementation should be reported (i.e., percent of time participant reported using strategy as it was designed to be implemented in intervention).

This review was also not able to report on potential harms of the interventions. As family-based, multicomponent behavioral interventions are considered to produce minimal harm, investigators rarely report on harms. However, to fully evaluate programs, potential physiological, as well as psychosocial (either to the child or the family), harms need to be routinely assessed and reported.

While one objective of this effort was to provide an update on research conducted on the efficacy of family-based, multicomponent behavioral interventions for treating child and adolescent overweight and obesity, other key questions focused on identifying factors that may be important for understanding how to successfully implement the intervention, who may benefit most from the intervention, what components of the intervention are most efficacious, and areas of patient engagement needed for successful outcomes. These types of questions may be best addressed by effectiveness trials, and in particular phase 3 translational trials, in which areas of intervention adoption, adaptation, and dissemination are examined (Czajkowski et al., 2016). As the systematic review found insufficient or low-quality research to address the key questions focused in this area, this indicates that more translational research is needed to better inform the development of clinical practice guidelines on weight management for children and adolescents.

To assist with translation, the field of childhood obesity treatment could benefit from using advances in behavioral research design, and the emerging literature on adaptive interventions is particularly promising. Adaptive interventions anticipate response heterogeneity and deploy intervention content depending on specific individual needs (Lei, Nahum-Shani, Lynch, Oslin, & Murphy, 2012). For example, adaptive interventions can change or enhance treatment dose for non-responders, re-introduce treatment for those who experience relapse, decrease or alter dose for those who are early responders, and/or differentially adapt dose by

treatment target (e.g., parent, childcare provider, teacher). Sequential, multiple assignment, randomized trials (SMARTs) (Lei et al., 2012) allow one to simultaneously test multiple adaptive interventions, along with decision rules for adapting treatment. With SMARTs, researchers can easily evaluate multiple intervention design options (e.g., dose, treatment type, delivery schedule, triggering events). SMARTs may have particular benefit to setting-specific childhood obesity treatments (i.e. school, childcare, primary care-based), in which population level treatments are necessary. Given ever-present resource constraints, SMARTs may also benefit efforts to identify how to best distribute treatment contact among patients and their families.

Furthermore, most childhood obesity treatments are essentially “packages” of varied behavioral intervention components. These components are often targeted at multiple levels (e.g., child, parent, family, household, school) and a range of theoretical mediators. A key barrier to improving treatment efficacy is our inability to break up these black box interventions to characterize the effect size of their discrete components. That is, traditional "gold-standard" RCT designs cannot reveal which intervention strategies contribute most to weight change, which might have limited influence, or which might even have detrimental effects. This limits one’s ability to refine, enhance, or replace discrete intervention strategies. The challenge is magnified, given the derivative nature of research-tested treatments; a strategy with suboptimal efficacy might proliferate through multiple intervention trials, cannibalizing degrees of freedom that might be devoted to testing novel strategies. Related, this challenge limits one’s ability to create lean, cost-efficient interventions that can be scaled and disseminated. Use of novel design frameworks, such as the Multiphase Optimization Strategy (MOST), can assist in building optimized treatment packages that only contain strategies that meaningfully affect weight change outcomes (Noser, Cushing, McGrady, Amaro & Huffhines, 2017). MOST involves using theory to identify testable intervention strategies, which are then subjected to an experimental trial (usually a factorial or fractional-factorial trial). Strategies meeting a pre-defined effect size are assembled into a treatment package, which can then be tested in a

standard randomized controlled trial. A key challenge facing investigations like the panel's is the need to discern the efficacy of treatment characteristics by examining largely non-comparable multicomponent interventions. Rather than relying solely on these post-hoc determinations of treatment component efficacy, MOST allows for the experimental determination of a component's efficacy prior to its implementation in a multicomponent package. In this way, one might more rapidly and systematically identify ways of enhancing treatment outcomes beyond solely increasing treatment dose.

Table 3: Items to Consider for Inclusion in Future Research Studies on Treatment Interventions Involving Children

Race and ethnicity
Socioeconomic status
Possible harms and other adverse events associated with treatment
Methodological details of components of the intervention program including implementation process, adherence and engagement
Outcome measures to include BMI/zBMI scores as well as standardized measures of self-efficacy, psychosocial outcomes, metabolic functioning and other outcomes when used
Other novel designs (i.e., SMARTs)

Conclusion

This guideline for the treatment of overweight and obesity in children and adolescents incorporates standards for trustworthy clinical practice guideline development from the former Institute of Medicine of the National Academy of Sciences (IOM, 2011a). Thus, this guideline follows standards required for inclusion in the National Guideline Clearinghouse. These standards include an emphasis on using a high quality systematic review, identification and management of conflicts of interest, transparency, and multidisciplinary panels. The

recommendations of this guideline are based on a rigorous systematic review that followed IOM (2011b) standards for systematic reviews. This guideline is unique in that it included patient values and preferences as well as information available, though limited, on harms and burdens of treatment.

The findings of this guideline are consistent with those of other published treatment guidelines for overweight and obesity and recommend family-based multicomponent behavioral interventions with at least 26 contact hours for children and adolescents with overweight or obesity. The guideline also recommends using these interventions, particularly with young children diagnosed with overweight or obesity. Panel members recognize that while these recommendations were made based on scientifically rigorous methods, future research is needed to address gaps in the current scientific literature. Several of these limitations include lack of information on the adiposity reduction amount needed to enhance other aspects of health in children and adolescents, lack of reporting of race and ethnicity as well as socioeconomic status of study participants, and no additional outcome measures beyond BMI/zBMI. Furthermore, information is needed on potential harms of interventions, methodological details of the intervention program (i.e., implementation process, adherence, and engagement, other novel designs) and comparative effectiveness of different change strategies.

Conflicts of Interest

Prior to final appointment to the panel, candidates completed a conflict of interest (COI) form that was then reviewed by the advisory steering committee or APA staff to ensure there were no identified conflicts that would prohibit participation, with the understanding that some "adversarial conflict" representing different points of views was to be expected and encouraged in this process. While intellectual affiliations were expected, no panel members had been singularly identified with particular approaches to intervention or had significant known financial conflicts. Once the panel was formed, all panel members completed an educational module on COI that underscored the importance of identifying and managing any potential conflicts, both financial and intellectual. The APA COI policy and disclosure form are included in the appendix.

All panel members and staff affiliated with development of the Obesity CPG updated their COI form on an annual basis and were asked to provide more timely updates if changes in their disclosures were perceived to be relevant to the development of the guideline. All were asked to disclose all potential COI with the understanding that these would be reviewed and evaluated and a decision would be made regarding how to manage identified conflicts. Conflicts of interest included not only possibilities for financial or professional gain but also strong intellectual viewpoints that might then limit someone from objectively reviewing the evidence. Emphasis was placed on disclosing all potential conflicts and allowing the staff and chair (or other appropriate entity in the case of the chair) to review the disclosures and determine whether or not such information could reasonably be construed as to be a source of possible influence on the guideline development process. Furthermore, upon first joining the initiative and at the initial face to face meeting, panel members were asked to verbalize their conflicts so all present would be familiar with the diversity of perspectives and range of possible influences. This practice continued at subsequent face-to-face meetings.

All authors were required to disclose their intellectual interests, financial and professional interests, interests related to APA, and other relevant interests. They were also

required to disclose interests of family members, defined as “a spouse, domestic partner, parent, child, or other relative with whom [they] have a comparably close tie.” Authors disclosed the following potential COI: scientific/educational/professional communications, communications to a general audience, roles at APA or other organizations, relevant honoraria, endorsements, research funding or royalties, payment for services or training, and serving as expert witnesses. None of the reported potential conflicts of interest precluded a nominated candidate from serving on the GDP. Excluding all GDP candidates with any potential COIs risks excluding the level and type of expertise needed to fully evaluate treatment benefits and risks. The most knowledgeable individuals can be conflicted because of expertise in their areas of interest, and they may possess both financial and intellectual COIs from participating in research and serving as consultants to industry. However, these experts may possess unique insight into appropriate health care needs and recommendations.

There is growing recognition that financial relations to the pharmaceutical industry threaten the integrity of research and of CPGs. However, the issue is still contentious, and exclusion of all potential GDP members with such conflicts may itself be seen as biased against pharmacological treatments or particular medical specialties. Similarly, experts with respect to psychotherapy tend to have intellectual passions for specific types of psychosocial interventions that also constitute potential conflicts. Yet, such individuals may be difficult to replace because of their unique insights, as well as their status in the eyes of key stakeholders (IOM, 2011b). Hence, rather than exclude topic experts and risk minimizing expertise, APA follows the principle of adversarial collaboration in which competing interests are balanced on panels and committees, rather than avoided. This approach is also used by other leading developer of CPGs, such as the ACCF/AHA task force (ACCF and AHA, 2008; IOM, 2011b).

Conflict of interest forms for all authors are available by request for public review.

Developer

American Psychological Association (APA)- Obesity Guideline Development Panel (GDP). The Obesity GDP is a multidisciplinary Panel of experts.

Author Disclosures

The Clinical Practice Guideline Panel reported the following disclosures during the development and approval of this guideline:

Maria M. Llabre, PhD (**Chair**), is a professor of psychology, associate chair for graduate studies and the director of biobehavioral statistics at the Behavioral Medicine Research Center at the University of Miami. She reports no conflicts of interest with her work on these guidelines.

Jamy Darone Ard, MD (**Vice-Chair**), is an associate professor in the department of epidemiology and prevention and the department of medicine at Wake Forest University Baptist Medical Center. He is also the co-director of the Wake Forest Baptist Health Weight Management Center. He regularly leads professional workshops and publishes on topics related to obesity and obesity treatment. He receives payment directly for providing or training other individuals to provide health services related to obesity, as well as honoraria for presentations, discussions, and royalties. He has received funding for research or research training on scientific or clinical issues related to obesity. He reports no conflicts of interest with his work on these guidelines.

Gary Bennett, PhD, is professor of psychology, global health, and medicine at Duke University. He directs the Duke Obesity Prevention Program and the Duke Global Digital Health Science. He regularly leads professional workshops and publishes on topics related to obesity. He receives honoraria for presentations and discussions, and has received funding for research or research training on scientific or clinical issues related to obesity. He holds equity stake in Scale Down, a company that markets a digital health weight loss product, as well as in Coeus

Health, a company that develops software that allows developers to more easily create evidence-based health applications including for obesity treatment. He reports no conflicts of interest with his work on these guidelines.

Phillip J. Brantley, PhD, is a John S. McIlhenny Professor and Head of Behavioral Medicine at the Pennington Biomedical Research Center at Louisiana State University in Baton Rouge. He also serves on the Executive Council of the Obesity Society. He reports no conflicts of interest with his work on these guidelines.

Barbara Fiese, PhD, is a professor of human development and family studies at the University of Illinois at Urbana-Champaign and director of the Family Resiliency Center. She regularly leads professional workshops and publishes on topics related to obesity. She receives honoraria for presentations, discussions, and royalties. She has received funding for research or research training on scientific or clinical issues related to obesity. She reports no conflicts of interest with her work on these guidelines.

Jane Gray, PhD, serves as the director of behavioral health for the Texas Center for the Prevention and Treatment of Childhood Obesity, an interdisciplinary pediatric weight management program in central Texas. She regularly leads professional workshops and publishes on topics related to obesity. She receives payment directly for providing or training other individuals to provide health services related to obesity. Currently, she is participating in the “Expert Exchange,” which is a collaboration between the Children’s Hospital Association and the American Academy of Pediatrics, focusing on targeting pediatric obesity in primary care, and addressing severe obesity. She reports no conflicts of interest with her work on these guidelines.

Patty Nece, JD, is the counsel for regulations and legislation in the U.S. Department of Labor’s Office of the Solicitor’s Division of Black Lung and Longshore Legal Services. She

regularly leads professional workshops on topics related to obesity. She receives honoraria for presentations and discussions. She reports no conflicts of interest with her work on these guidelines.

Michele Polfuss, PhD, RN, CPNP-AC/PC, is a pediatric nurse practitioner and assistant professor. Currently, she works at the University of Wisconsin – Milwaukee College of Nursing and holds the position of Joint Research Chair in the Nursing of Children between the University of Wisconsin-Milwaukee and Children's Hospital of Wisconsin. She has experience leading professional workshops and publishes on topics related to obesity. She receives honoraria for presentations and discussions on obesity. She is an active researcher who has received funding for research or research training on scientific or clinical issues related to childhood obesity and obesity in developmental disabilities. She serves as the project leader of a group within the National Association of Pediatric Nurse Practitioners that is updating its own clinical practice guidelines on obesity. In 2015, she joined the "Healthy Weight Research Network," researching obesity in individuals with developmental disabilities and autism. She reports no conflicts of interest with her work on these guidelines.

Hollie Raynor, PhD, RD, LDN, is a registered dietician and clinical psychologist. She is an associate professor in the department of nutrition at the University of Tennessee. She regularly leads professional workshops and publishes on topics related to obesity. She receives honoraria for presentation and discussions on obesity. She has received research funding from Weight Watchers International for research in adult weight management. She reports no conflicts of interest with her work on these guidelines.

Delia Smith West, PhD, is a South Carolina SMART State Endowed professor of exercise science, and the director of the Technology Center to Promote Healthy Lifestyles at the University of South Carolina. She regularly leads professional workshops and publishes on

topics related to obesity. She receives payment directly for providing or training other individuals to provide health services related to obesity as well as honoraria for presentations and discussions. She has received research funding from the National Institute for Health (NIH). She reports no conflicts of interest with her work on these guidelines.

Denise Wilfley, PhD, is a Scott Rudolph University professor of psychiatry, medicine, pediatrics, and psychology at Washington University in St. Louis. She regularly leads professional workshops and publishes on topics related to obesity. She receives payment directly for providing or training other individuals to provide health services related to obesity as well as honoraria for presentations and discussions. Currently, she is the principal investigator on an NIH/NHLBI T32 training grant called, “Nutrition-Behavioral Cardiovascular Disease Prevention.” She is on the Advisory Board for several obesity-related centers, and has held or currently serves in leadership roles for several scientific and advocacy organizations addressing the topic of obesity. She reports no conflicts of interest with her work on these guidelines.

Conflict of interest forms for all authors are available by request for public review.

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Appendices

Appendix A
Definitions of Key Terms

Advisory Steering Committee (ASC). The Advisory Steering Committee is a group of distinguished psychologists appointed by the APA Board of Directors (BOD) to oversee APA's CPG development process. The ASC selects which nominated topics will be considered for guidelines and assembles the Panels who write the guidelines, but they are not directly involved in conducting SRs, nor in writing CPGs. In addition, while the ASC reports to the BOD and was initially constituted by a subcommittee representing the Board of Professional Affairs (BPA), the Board of Scientific Affairs (BSA), and the Committee for the Advancement of Professional Practice (CAPP), the ASC operates autonomously from APA governance to prevent real or perceived COIs.

Agency for Healthcare Research and Quality (AHRQ). One of 12 agencies within the Department of Health and Human Services, AHRQ supports research that helps people make more informed decisions and improves the quality of health care services. AHRQ's mission is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans, with the following focus areas: comparing the effectiveness of treatments; quality improvement and patient safety; health information technology; prevention and care management; and health care value. AHRQ develops systematic reviews on topics of greatest public health impact. Topic nomination is an open process through AHRQ's Effective Healthcare Program; APA plans to use this mechanism to support SRs for CPG development.

Applicability. Applicability is analogous to external validity or generalizability (IOM, 2011a). Consideration of such is consistent with the aim of helping consumers, clinicians, purchasers, and policy makers make informed that decisions that will improve health care at both the individual and population levels.

Benefit. A positive or valued outcome of an action or event. (IOM, 2011a).

Bias. A systematic deviation or process that favors one outcome over others (Gluud, 2006). Bias may lead to under- or over-estimation of treatment effects. It is impractical and most likely impossible to quantify every potential source of bias that may influence an individual study (Chavalarias & Ioannidis, 2010); however, a number of specific methodological flaws or limitations in research design, implementation, analysis, and evaluation often produce biased outcomes.

Comparative effectiveness research (CER). The generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to help consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels. Also referred to as clinical effectiveness research (IOM. 2011a).

Confidence interval (CI). A confidence interval is a range around an estimate that conveys how precise the estimate is; for example, an estimate of the risk of an event occurring or an estimate such as a risk ratio that compares the risk with and without an intervention. The confidence interval is a guide to how sure we can be about the quantity we are interested in. The narrower the range between the two numbers, the more confident we can be about what the true value is; the wider the range, the less sure we can be. The width of the confidence interval reflects the extent to which chance may be responsible for the observed estimate (with a wider interval reflecting more

chance). 95% Confidence Interval (CI) means that we can be 95 percent confident that the true size of effect is between the lower and upper confidence limit. Conversely, there is a 5 percent chance that the true effect is outside of this range (DECIDE, 2012).

Effectiveness. The impact of an intervention compared to active treatment.

Efficacy. The impact of an intervention compared to an inactive control.

Estimate of effect. The observed relationship between an intervention and an outcome expressed as, for example, a number needed to treat to benefit, odds ratio, risk difference, risk ratio, standardized mean difference, or weighted mean difference.

Evidence. Information on which a decision or guidance is based. Evidence is obtained from a range of sources, including randomized controlled trials, observational studies, and expert opinion of clinical professionals or patients (IOM, 2011b).

Evidence Tables. Abstracts of data included in the systematic review and include, as available for each body of evidence, the number of studies, effect sizes, confidence intervals (when available) and quality ratings

GRADE (GRADE collaboration and Framework). The Grading of Recommendations Assessment, Development and Evaluation (GRADE) Consortium Working Group, which began in the year 2000, is an international collaboration of scholars with an interest in addressing the shortcomings of present grading systems for CPGs in health care. The working group has developed a sensible and transparent framework for grading strength of evidence and strength of recommendations, typically referred to as "GRADE" (or the GRADE system). Many international organizations provided input into the development of the approach and have started using it (for further information, see http://www.gradeworkinggroup.org/).

Grid. A document developed and used by panel members to summarize and evaluate the evidence generated in the systematic review, along with any supplemental information.

Guideline Development Panel (GDP). A multidisciplinary Guideline Development Panel is assembled for the purpose of developing a specific CPG. GDPs are tasked with generating treatment recommendations from systematic reviews, and drafting the content of the CPGs. These activities take place independently from APA governance/staff, the ASC, and Systematic Review Teams, who play no part in developing the CPG recommendations. There is some interaction between the SRT and GDP to ensure that the systematic review will meet the needs of the CPG developers; yet, the nature of the interaction is transparent and circumscribed to maintain the objectivity and validity of both the systematic review and the CPG.

Harm. A hurtful or adverse outcome of an action or event, or with regard to CPGs, a treatment or health care decision/recommendation, whether temporary or permanent (IOM, 2011b).

Institute of Medicine (IOM). A private, nonprofit institution that provides objective, timely, authoritative information and advice concerning health and science policy to the government, the corporate sector, the professions, and the public under a congressional charter.

Meta-analysis. The use of quantitative statistical methods in a systematic review to integrate the results of included studies.

Outcome. A change resulting from an intervention. In evaluations, a potential consequence of an intervention that is measured after the intervention has been implemented, that is used to assess

the potential beneficial and harmful effects of the intervention. **Critical outcomes** are the outcomes of greatest importance for answering key questions in systematic reviews (Boyd et al., 2012).

Patient-centeredness. Respect for and responsiveness to individual patient preferences, needs, and values; helps ensure that patient values and circumstances guide clinical decisions (IOM. 2011a).

PICOTS (questions) - Systematic reviews seek to answer clearly formulated key questions that will simplify decision-making about real world practices, and thereby inform CPG recommendations. These key questions are developed using the PICOTS framework, an acronym denoting components that should be specified in each key question: Patient populations (P), Interventions (I), Comparison conditions (C), Outcomes (O), Timing or timeframe (T), and Settings (S). For this reason, the key questions in systematic reviews are frequently referred to as *PICOTS* (or *PICOTS questions)*. *Timing* and *Settings* are newer additions to the framework; hence, key questions may also be called PICOS (or PICO questions) by some investigators.

Publication bias. A bias caused by only a subset of all the relevant data being available. The publication of research can depend on the nature and direction of the study results. Studies in which an intervention is not found to be effective are sometimes not published. Because of this, systematic reviews that fail to include unpublished studies may overestimate the true effect of an intervention. In addition, a published report might present a biased set of results (e.g. only outcomes or sub-groups where a statistically significant difference was found).

Quality of evidence. The extent to which one can be confident that the estimates of an intervention's effectiveness are adequate to support a particular decision or recommendation (IOM, 2011b; Schünneman et al., 2011). AHRQ uses “strength of evidence” (SOE) to refer to the same basic concept.

Randomized controlled trial (RCT). An experiment in which two or more interventions, often including a control intervention or no intervention, are compared by randomly allocating participants to the interventions. The term ‘trial’ is sometimes used to refer to randomized controlled trials (RCTs); however, the term may also be used to refer to quasi-randomized trials (which do not randomly assign participants to groups).

Relative Effects. A quantitative measure for evaluating harms and benefits of treatment, expressed as the ratio of two indicators of the frequency of the outcome. A *risk ratio* (RR) is the ratio between the risk (incidence) of the outcome event in the intervention group and the risk in the control group. For example, if the risk of the outcome event in the intervention group is 5% (5 per 100) and the risk in the control group is 20% (10 per 100), the RR is .05 / .20 = .25. If the RR is less than 1, the risk of the outcome event in the intervention group is less than the control group. If the RR is equal to 1, the risk in the two groups is equal. If the RR is greater than 1, the intervention increases the risk of the outcome compared to the control group.

An odds ratio (OR) is also a measure of relative effects, in this case, the odds (not risk) in the intervention group compared to the odds (not risk) in the control group. An odds is a mathematical formula for the probability of an event happening divided by the probability of that event not happening or, mathematically: odds = p / (1-p). Thus, if the risk in the intervention group is 5% (i.e., .05), then the odds in the intervention group is .05 / .95 = .05 (with rounding). If the risk in the control group is .20, then the odds in the control group is .20 / .80 = .25. The odds ratio is then .05 / .25 = .20. Odds ratios can be interpreted similarly to risk ratios. However, when the risk of the outcome event is high, the odds ratio will be different from the risk ratio.

Risk of bias. The extent to which flaws in the design and execution of a collection of studies could bias the estimate of effect for each outcome under study (IOM, 2011b).

Strength of Evidence. The extent to which one can be confident that the estimates of an intervention's effectiveness are adequate to support a particular decision or recommendation (IOM, 2011b; Schünneman et al., 2011). GRADE uses “quality of evidence” to refer to the same basic concept.

Strength of Recommendation. The strength of a recommendation reflects the extent to which one can be confident that the desirable outcomes of a treatment alternative outweigh the undesirable outcomes, across the range of patients to whom the recommendations apply (IOM, 2011b; Schünneman et al., 2011).

Study Quality. For an individual study, study quality refers to all aspects of a study’s design and execution and the extent to which bias is avoided or minimized. A related concept is internal validity; that is, the degree to which the results of a study are likely to be true and free of bias (IOM, 2011b).

Systematic Review (SR) - A rigorous approach to synthesizing data from research studies on the benefits, harms and effectiveness of alternative treatment options that pertain to a particular clinical population (IOM, 2011b). Systematic reviews use pre-specified criteria for screening, selecting, appraising, grading, and synthesizing outcomes, from a body of research studies, to answer specific clinical questions in areas of uncertainty. SRs seek to minimize bias by using explicit, standardized procedures (Green et al., 2008). The use of standardized criteria enhances the reliability of the findings and confidence in the conclusions about the relative advantages of alternate treatment approaches (IOM, 2011a).

Transparency. Methods are explicitly defined, consistently applied, and available for public review so that observers can readily link judgments, decisions, or actions to the data on which they are based. Allows users to assess the strengths and weaknesses of the systematic review or CPG (IOM, 2011a).

Treatment Recommendation. In the context of CPGs, treatment recommendations are statements that propose a course of action with respect to a specific health care service, test, therapy, or procedure. Well-constructed recommendations specify what should be offered or provided to patients, as well as under what specific conditions the recommendation applies (Rosenfeld & Shiffman, 2009; Shiffman, 2009). In addition, the IOM (2011b) specifies that CPG recommendations should include alternative treatment options.

Appendix B

APA Declarations/COI Form

American Psychological Association

Clinical Practice Guideline Initiative

CONFLICT OF INTEREST POLICY

and

DECLARATION OF INTERESTS

2015

Covered Individual (please type your name and current date)

Name:

Date:

Please indicate with an 'X' your role(s) in the initiative:

___ Advisory Steering Committee (ASC) Member

___ Guideline Development Panel (GDP) Member

→ *If GDP Member, please name the topic of the Panel:*

___ Consultant

___ APA Staff Member

Instructions:

Please read the Conflict of Interest Policy, fill out the Declaration of Interests, and sign the statement at the end.

Conflict of Interest Policy

It is the aim of the American Psychological Association ("APA") to transact all of its business, including the APA clinical practice guideline initiative, lawfully and impartially. In some situations, the relationship of a Covered Individual (as defined below) with a third party, financial or otherwise, could reasonably be construed to create a conflict between the interests of APA and the interests of the Covered Individual.

Covered Individuals are required to disclose to APA any actual, potential, or perceived conflict of interest (COI) with APA or with their role in the clinical practice guideline initiative, including conflicts from the past 12 months and expected conflicts in the upcoming 12 months. A COI may be of a financial, intellectual, or other nature, as defined below. APA requires Covered Individuals to disclose COIs prior to official appointment to a committee/Panel or as a consultant, as well as at the time points noted below. The existence of COIs will not necessarily preclude participation in the guideline initiative, although it may require limiting a Covered Individual's role. APA staff involved in the initiative may also be asked by their supervisors to disclose COIs, following the same policy as for Covered Individuals.

This policy is designed to promote transparency, to protect the integrity of the guideline initiative, and to provide a mechanism to help protect Covered Individuals and APA from legal concerns associated with conflicts of interest.

Covered Individuals: This policy applies to members of the Advisory Steering Committee and the Guideline Development Panels of the APA clinical practice guideline initiative and to consultants who are formally engaged by APA for work on the initiative.

Term: Covered Individuals shall be bound by this conflict of interest policy during the official term of their position on the committee/Panel or as a consultant.

Definition of COI: A 2011 report from the Institute of Medicine includes the following definition of COI: "a divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing." (See Institute of Medicine, 2011, p. 78; the definition is drawn from Schünemann et al., 2009, p. 565.)

The Institute of Medicine report also discusses intellectual COIs relevant to clinical practice guidelines, which it defines as "academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation" (Institute of Medicine, 2011, p. 78; this definition is drawn from Guyatt et al., 2010, p. 739.)

COIs can arise in various situations and may involve the individual or a member of the individual's family (spouse, domestic partner, parent, child, or other close relative). Examples of potential COIs include, but are not limited to, the following:

Receiving payment for directly providing, or training other professionals to provide, health services related to the topic(s) of the guideline(s) being developed.
Receiving honoraria for presentations or discussions of scientific or clinical issues related to the topic(s) of the guideline(s) being developed.

Receiving royalties for books or other materials that address scientific or clinical issues related to the topic(s) of the guideline(s) being developed.
Receiving funding, in the form of grants or contracts, for research on scientific or clinical issues related to the topic(s) of the guideline(s) being developed.
Serving in a governance or other volunteer position in an organization that provides health services, promotes research related to health services, or develops or advocates for health service policies, related to the topic(s) of the guideline(s) being developed.
Having strongly held opinions or other intellectual biases that might compromise objectivity in addressing the topic(s) of the guideline(s) being developed.
Having a significant ownership interest in or significant capacity to influence decisions of a firm or organization that is an APA competitor, customer, or supplier, or a firm that conducts research or provides health services related to the topic(s) of the guideline(s) being developed.
Being employed by or performing other work (including consulting) for a competitor, customer, or supplier of APA, regardless of the nature of that work.
Conduct of APA business of any kind, or arranging for such business, with a firm that one owns or controls.
Acceptance of any money, property, or anything of value from a person or firm doing or seeking to do business with APA.
Receipt of direct or indirect economic benefit as a consequence of acquisition, lease, or sale by APA of any property, facilities, materials, or services.

COI Reporting: Covered Individuals must complete a Declaration of Interests form (appended below) disclosing any actual, potential, or perceived COIs prior to appointment to a committee/Panel or as a consultant, and thereafter on an annual basis. If, during the year, a change occurs in a Covered Individual's COIs or in his/her family members' COIs, the Covered Individual must report that information immediately to APA staff who work on the clinical practice guideline initiative, who will share it with the relevant committee/Panel Chair or Vice Chair. Covered Individuals are expected to provide any updates regarding their COIs orally at the beginning of all official committee/Panel meetings.

In addition, Covered Individuals should disclose any professional papers or presentations on which they are listed as authors, prior to publication or delivery, that pertain to the topic(s) of the guideline(s) with which they are involved. This disclosure should be made to APA staff involved in the initiative.

If a Covered Individual is unsure whether particular information should be reported, or if the information is sensitive or confidential, the Individual may first consult with APA staff involved in the initiative about whether and how to report it. With the individual's permission, the staff may then seek further guidance from the Chair or Vice Chair of the relevant committee/Panel.

Disclosure of any actual, potential, or perceived COI is the responsibility of everyone participating in the clinical practice guideline initiative. In general, if any Covered Individual or APA staff member is aware of circumstances that may constitute a COI involving another participant in the initiative, then he/she should first discuss it with that participant. If such a discussion is not appropriate or if the discussion does not produce a satisfactory result, then he/she should discuss it with APA staff and/or the relevant committee/Panel Chair or Vice Chair.

COI Review and Management: Each Covered Individual's completed Declaration of Interests form will be reviewed by APA staff and by the Chair and/or Vice Chair of the relevant committee/Panel (or only by APA staff for consultants). The individual's résumé or curriculum vitae, as well as publicly available materials about the individual, may also be examined in the

course of the review. The primary purpose of the review is to determine whether the individual has any actual, potential, or perceived COIs that would preclude the individual from participation in the clinical practice guideline development initiative or require resignation from any role that he/she already has in the initiative.

Having one or more COIs does not necessarily mean that a Covered Individual cannot be involved in the initiative. If the reviewers determine that an individual's COIs do not preclude participation, then the reviewers will identify what actions, if any, may be needed to resolve or manage the impact of the COIs on the integrity (both actual and perceived) of the initiative. Examples of such actions may include limitations on the individual's participation in discussions, deliberations, or voting on specific matters and not being counted in determining a quorum for all or portions of a particular committee/Panel meeting. Such actions would not prevent the individual from briefly stating his/her position or answering questions on relevant matters. Possible actions for managing the impact of COIs will be discussed with the Covered Individual, but final decisions on which actions are taken are made by APA staff in consultation with the relevant committee/Panel Chair and/or Vice Chair. In some cases, the APA General Counsel may participate in making such decisions. Also, in some cases in which the Covered Individual is a member of a Guideline Development Panel or a consultant, the Chair and/or Vice Chair of the Advisory Steering Committee may participate in making such decisions.

If any new COIs are reported or discovered during the period after a Declaration of Interests form has been submitted, APA staff and the relevant committee/Panel Chair and/or Vice Chair will determine whether any further actions are required for managing their impact on the initiative.

For Covered Individuals who are members of a committee/Panel, information about all actual, potential, and perceived COIs are shared with all other members of the committee/Panel. Information about all actions taken to resolve or manage the impact of COIs are also shared with all members of the committee/Panel.

Record of COIs: APA retains a copy of all completed Declaration of Interests forms and related documents. Summary information about Covered Individuals' COIs and of actions taken to manage their impact will be available for public view. (No information will be publicly released about people who are nominated or considered for positions on a committee/Panel or as consultants but not selected.) Additional information about COIs and actions taken may appear in meeting minutes and summaries, which will also be available for public view. It is also possible that additional information will be made public in response to inquiries.

References

Guyatt, G., Akl, E. A., Hirsh, J., Kearon, C., Crowther, M., Gutterman, D., Lewis, S. Z., Nathanson, I., Jaeschke, R., & Schünemann, H. (2010). The vexing problem of guidelines and conflict of interest: A potential solution. *Annals of Internal Medicine, 152*(11), 738–741.

Institute of Medicine (2011). *Clinical practice guidelines we can trust*. Washington, DC: National Academies Press.

Schünemann, H. J., Osborne, M., Moss, J., Manthous, C., Wagner, G., Sicilian, L., Ohar, J., McDermott, S., Lucas, L., & R. Jaeschke. (2009). An official American Thoracic Society policy

statement: Managing conflict of interest in professional societies. *American Journal of Respiratory Critical Care Medicine, 180*(6), 564–580.

Declaration of Interests

The purpose of this Declaration is to identify your actual, potential, and perceived conflicts of interest with APA and with your role in the APA clinical practice guideline initiative. Having conflicts of interest does not necessarily preclude participation in the initiative. Decisions about how conflicts should be managed will be made by APA staff in consultation with the Chair or Vice Chair of any committee or Panel of which you are a member.

Please answer the following questions by marking either 'Yes' or 'No' and then explaining any 'Yes' answers in the space immediately following or by attaching supplementary materials. When responding, please think about the full range of research, teaching, practice, writing, service work, and professional relationships in which you and your family members are involved. (You may consult with APA staff in advance if you have any questions or concerns about what information to provide on this form.)

The questions are organized into four sections:

- *Intellectual Interests*
- *Financial and Professional Interests*
- *Interests Related to APA*
- *Other Relevant Interests*

For the purposes of this Declaration, a family member is a spouse, domestic partner, parent, child, or other relative with whom you have a comparably close tie.

Please attach a CV, résumé, or other materials if these are needed to provide complete answers.

(Questions begin on next page.)

INTELLECTUAL INTERESTS

(The questions in this section concern only you, not family members.)

1. Scientific/educational/professional communications

Over the past 12 months, have you had any scientific, educational, or professional publications (including in-press) or made any scientific, educational, or professional presentations related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing? Has your name been included on a relevant speakers' bureau list? Please include both paid and non-paid work.

___ Yes ___ No

Do you expect that, over the next 12 months, you will have any such publications or presentations or that your name will be included on a speakers' bureau list?

___ Yes ___ No

If 'Yes' to any of these questions, please provide a list of the relevant publications, presentations, courses, and speakers' bureaus. You may attach a copy of your CV or résumé but please make sure to add any items that do not yet appear on those documents.

[Insert material here]

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2. Communications with general audiences

Over the past 12 months, have you made presentations to a general (non-academic, non-scientific) audience that address research, clinical, or policy issues related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing? Have you been involved in organizing any events that include such presentations?

___ Yes ___ No

Over the past 12 months, have you published articles or books for a general audience or produced materials for television, radio, or the Internet (e.g., blogs, online petitions, Facebook, LinkedIn, TED Talks, Twitter, YouTube) that address these issues? Please include both paid and non-paid work. You need not include formal research publications for academic or scientific audiences.

___ Yes ___ No

Do you expect that, over the next 12 months, you will be involved in any such activities?

___ Yes ___ No

If 'Yes' to any of these questions, please provide a list of the presentations and published/posted materials. You may attach a copy of your CV or résumé but please make sure to add any items that do not yet appear on those documents.

[Insert material here]

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3. Expert witness

Over the past 12 months, have you served as an expert witness in a court case or other legal proceeding on a matter related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing?

___ Yes ___ No

Do you expect that, over the next 12 months, you will serve as an expert witness in a legal proceeding?

___ Yes ___ No

If 'Yes' to either question, please explain:

[Insert material here]

FINANCIAL AND PROFESSIONAL INTERESTS

(The questions in this section concern both you and family members. For the purposes of this Declaration, a family member is a spouse, domestic partner, parent, child, or other relative with whom you have a comparably close tie.)

4. Payment for services or training

Over the past 12 months, have you or a family member received payment for directly providing, or training other individuals to provide, health services related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing? (Health services include professional, community-based, and peer support services.)

___ Yes ___ No

Do you expect that, over the next 12 months, you or a family member will receive any payment for such activity?

___ Yes ___ No

If 'Yes' to either question, please explain:

[Insert material here]

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5. Honoraria

Over the past 12 months, have you or a family member received any honoraria for presentations or discussions of scientific or clinical issues related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing? (Please include honoraria that were donated to charity.)

___ Yes ___ No

Do you expect that, over the next 12 months, you or a family member will receive any such honoraria?

___ Yes ___ No

If 'Yes' to either question, please explain:

[Insert material here]

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6. Royalties

Over the past 12 months, have you or a family member received royalties or advance payments for books, films, or other materials that address scientific or clinical issues related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing? (Please include royalties that were donated to charity.)

___ Yes ___ No

Do you expect that, over the next 12 months, you or a family member will receive any such royalties or advance payments?

___ Yes ___ No

If 'Yes' to either question, please explain:

[Insert material here]

---

7. Endorsements

Over the past 12 months, have you or a family member received monetary or other material compensation for endorsing a product or service related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing? (Please include compensation that was donated to charity.)

___ Yes ___ No

Do you expect that, over the next 12 months, you or a family member will receive such compensation for an endorsement?

___ Yes ___ No

If 'Yes' to either question, please explain:

[Insert material here]

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8. Research funding

Over the past 12 months, have you or a family member received funding, in the form of grants, fellowships, or contracts, for research or research training on scientific or clinical issues related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing?

___ Yes ___ No

Do you expect that, over the next 12 months, you or a family member will receive any such funding?

___ Yes ___ No

If 'Yes' to either question, please explain:

[Insert material here]

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9. Employer

Over the past 12 months, have you or a family member held a job with an employer that has economic, policy, or other interests in healthcare guidelines in general or in the particular topic(s) of the guideline(s) that you will be involved in developing or overseeing? (Please consider both full- and part-time positions and both permanent and temporary positions.)

___ Yes ___ No

Do you expect that, over the next 12 months, you or a family member will hold a job with an employer that has such interests?

___ Yes ___ No

If 'Yes' to either question, please explain:

[Insert material here]

---

10. Roles in organizations

Over the past 12 months, have you or a family member served in a governance, advisory, or other position in an organization (other than APA) that provides health services, promotes research related to health services, or develops or advocates for health service policies, related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing?

___ Yes ___ No

Do you expect that, over the next 12 months, you or a family member will serve in such a position?

___ Yes ___ No

If 'Yes' to either question, please explain:

[Insert material here]

---

11. Influence/ownership/stock in health-related firms

Over the past 12 months, have you or a family member had a significant capacity to influence decisions of a firm or organization that conducts research or provides health services related to the topic(s) of the guideline(s) being developed? (Health services include professional, community-based, and peer support services.)

___ Yes ___ No

Over the past 12 months, have you and/or any family member(s) held an ownership interest greater than 5% in such a firm? Have you and/or any family member(s) owned stock in such a firm that exceeded $10,000 in value at any time during the past 12 months? (Please consider the total amounts held by you and family members, e.g., whether the stock that your spouse and your parent own adds up to more than $10,000 in value.)

___ Yes ___ No

Do you or any family member hold stock options of any value in such a firm?

___ Yes ___ No

Do you expect that, over the next 12 months, you or a family member will have such capacity to influence a firm or have such ownership or stock interests?

___ Yes ___ No

If 'Yes' to any of these questions, please explain:

[Insert material here]

INTERESTS RELATED TO APA

(The questions in this section concern both you and family members. For the purposes of this Declaration, a family member is a spouse, domestic partner, parent, child, or other relative with whom you have a comparably close tie.)

12. APA roles

Over the past 12 months, have you or a family member been a member of any APA governance group, task force, or advisory body? (Please include roles in APA divisions.)

___ Yes ___ No

Do you expect that, over the next 12 months, you or a family member will serve as a member of such an APA group?

___ Yes ___ No

If 'Yes' to either question, please explain:

[Insert material here]

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13. Influence/ownership/stock in firms of interest to APA

Over the past 12 months, have you or a family member had a significant capacity to influence decisions of a firm or organization that is an APA competitor, customer, or supplier?

___ Yes ___ No

Over the past 12 months, have you and/or any family member(s) held an ownership interest greater than 5% in such a firm? Have you and/or any family member(s) owned stock in such a firm that exceeded $10,000 in value at any time during the past 12 months? (Please consider the total amounts held by you and family members, e.g., whether the stock that your spouse and your parent own adds up to more than $10,000 in value.)

___ Yes ___ No

Do you or any family member hold stock options of any value in such a firm?

___ Yes ___ No

Do you expect that, over the next 12 months, you or a family member will have such capacity to influence a firm or have such ownership or stock interests?

___ Yes ___ No

If 'Yes' to any of these questions, please explain:

[Insert material here]

---

14. Paid work with other firms that do business with APA

Over the past 12 months, have you or a family member been employed by or performed other work (including consulting) for a competitor, customer, or supplier of APA, regardless of the nature of that work?

___ Yes ___ No

Do you expect that, over the next 12 months, you or a family member will be engaged in such employment or work?

___ Yes ___ No

If 'Yes' to either question, please explain:

[Insert material here]

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15. Business ties to APA

Over the past 12 months, have you or a family member conducted APA business of any kind, or arranged for such business, with a firm that is owned or controlled by you or a family member?

___ Yes ___ No

Do you expect that, over the next 12 months, you or a family member will conduct or arrange for such business?

___ Yes ___ No

If 'Yes' to either question, please explain:

[Insert material here]

---

16. Ties to others seeking business with APA

Over the past 12 months, have you or a family member accepted any money, property, or anything of value from a person or firm doing or seeking to do business with APA?

___ Yes ___ No

Do you expect that, over the next 12 months, you or a family member will accept any money, property, or anything of value from a person or firm doing or seeking to do business with APA?

___ Yes ___ No

If 'Yes' to either question, please explain:

[Insert material here]

---

17. Other economic benefits related to APA business

Over the past 12 months, have you or a family member received any direct or indirect economic benefit as a consequence of acquisition, lease, or sale by APA of any property, facilities, materials, or services?

___ Yes ___ No

Over the past 12 months, have you or a family member received any other direct or indirect economic benefit related to APA business that are not covered in the previous questions?

___ Yes ___ No

Do you expect that, over the next 12 months, you or a family member will receive any such economic benefit?

___ Yes ___ No

If 'Yes' to any of these questions, please explain:

[Insert material here]

OTHER RELEVANT INTERESTS

(The questions in this section concern both you and family members. For the purposes of this Declaration, a family member is a spouse, domestic partner, parent, child, or other relative with whom you have a comparably close tie.)

18. Other professional activities

Over the past 12 months, have you or a family member engaged in any other scientific, academic, clinical, business, or policy activities, either paid or unpaid, related to the topic(s) of the guideline(s) that you will be involved in developing or overseeing? (This question is asking about activities not already addressed in answers to the previous questions.)

___ Yes ___ No

Do you expect that, over the next 12 months, you or a family member will engage in other such activities?

___ Yes ___ No

If 'Yes' to either question, please explain:

[Insert material here]

----

19. Legal proceedings

At any point over the last 12 months, have you or a family member been under prosecution for a crime? Have you or a family member been involved in any civil legal proceedings as either defendant or plaintiff? (Please include all such legal proceedings, including those not related to the topic(s) of the guideline(s) you will be involved in developing or overseeing.)

___ Yes ___ No

If 'Yes' to either question, please explain:

[Insert material here]

---

20. Misconduct

At any point over the last 12 months, have you or a family member been formally charged with ethical, professional, or financial misconduct by any organization? (Please include all such charges, including those not related to the topic(s) of the guideline(s) you will be involved in developing or overseeing.)

___ Yes ___ No
If 'Yes," please explain:

[Insert material here]

---

21. Additional activities

Is there any other information regarding your or family members' activities, including interactions with organizations and individuals, that you believe is relevant to the guideline(s) that you will be involved in developing or overseeing or to your working with APA? Please focus on activities that may constitute actual, potential, or perceived conflicts of interest, and include activities that occurred *more* than 12 months ago or are expected to occur *more* than 12 months from now.

___ Yes ___ No

If 'Yes," please explain:

[Insert material here]

---

22. Relationships

Do you have any concerns that your work on guideline development or with APA could have a significant negative impact on any professional or personal relationships you have with mentors, students, trainees, colleagues, supervisors, funders, friends, or relatives? (For this question, please consider all relatives in addition to spouse, domestic partner, parents, and children.)

___ Yes ___ No

If 'Yes,' please explain:

[Insert material here]

Finally, please read, complete, and sign the following statement:

I have read and I understand the requirements of APA's Conflict of Interest Policy above and I agree to abide by the Policy throughout the official term of my position in the APA clinical practice guideline initiative.

I have also fully and truthfully answered the questions in the Declaration of Interests above about all actual, potential, and perceived conflicts of interest.

If any new actual, potential, or perceived conflicts of interest arise, I agree to disclose them immediately to APA staff and to the Chair or Vice Chair of any committee or Panel of which I am a member.

_____ _____

Signature (type name) **Date**

Please email this document to Ms. Shannon Beattie at: sbeattie@apa.org

REMINDER: ***Please attach a CV, résumé, or other materials if these are needed to provide complete answers.***

For APA Staff Use Only

Appendix C

Voting Procedures Established by Advisory Steering Committee (ASC)

1) What % should be considered a majority for winning a vote?

The ASC agreed that at least 70% of the whole constituted panel would constitute a strong recommendation. For conditional recommendations, agreement among more than 50% with less than 20% of panel members preferring an alternative recommendation must be reached. The denominator for voting will be the number of the entire panel membership, except in special cases, to be determined by the ASC. Such cases could include the lack of participation by a particular member in the guideline development process. APA staff will consult with ASC liaisons to panels as needed regarding special cases. However, panel members who are normally participatory, but have missed crucial conversations and/or votes due to extenuating circumstances, will still be allowed to share their opinions.

2) Should dissenting opinions from members that disagree be added to recommendation statements?

The ASC agreed that there may be a section in final guideline documents for any dissenting opinions that panel members have. A footnote will disclose the number of dissenting panel members and possibly their names.

Appendix D

Other Organizations' Clinical Practice Guidelines on Overweight and Obesity in Children and Adolescents

AACE/ACE Obesity Task Force (1998). AACE/ACE Position statement on the prevention, diagnosis, and treatment of obesity. *Endocrine Practice, 4*(5).

AHA/ACC/TOS (2013). 2013 AHA/ACC/TOS Guideline for the management of overweight and obesity in adults: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. *Circulation, 129*(25). doi: 10.1161/01.cir.0000437739.71477.ee

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Appendix E

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