OHSU Partners
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OFFICE OF CLINICAL INTEGRATION AND EVIDENCE-BASED PRACTICE

Evidence-Based Practice Summary
Pediatric Obesity Management Program

Prepared for: Louise Vaz, MD, MPH, Pediatrics
Authors: Marcy Hager, MA

BACKGROUND

Effective strategies to address the prevention and treatment of childhood obesity are critical to improving the health of the US population. In 2014, the Centers for Disease Control and Prevention (CDC) reported 17% of children and adolescents between the ages of 2 – 19 years were considered obese (CDC, 2015). Chronic diseases that once only affected adults such as hypertension, type II diabetes, and lipid disorders are now being diagnosed in young children who are overweight and obese (Han, 2010). In the short term, obesity poses significant risks for children's physical health and psychological well-being. In the long term, many children will continue to be obese into their adulthood if it is not addressed (Olshansky, 2005).

ASK THE QUESTION

What are best practices for establishing a comprehensive obesity management program in the clinical setting (including physical therapy, social work, nutrition, etc.) for pediatric patients (< 21 years) to contribute to long-term weight maintenance?

SEARCH FOR EVIDENCE

Databases included Ovid MEDLINE, Cochrane Database of Systematic Reviews, PsycINFO, and National Guideline Clearinghouse, also looked at references and citing articles

Ovid MEDLINE search strategy included:

1. exp Obesity/di, dh, dt, nu, pc, su, th [Diagnosis, Diet Therapy, Drug Therapy, Nursing, Prevention & Control, Surgery, Therapy] (64524)
2. exp body weight/ (411774)
3. exp bariatrics/ (19747)
4. exp bariatric medicine/ (60)
5. 1 or 2 or 3 or 4 (419145)
6. exp Practice Management/ (33003)
7. 5 and 6 (38)
8. exp personnel management/ (138838)

9. (1 or 3 or 4) and 8 (295)
10. 7 or 9 (332)
11. ((build* or launch* or establish* or create* or creating or ((plan* or staff* or employee* or salar* or fte) adj5 (administr* or organiz* or oversee*))) adj10 ((bariatr* or overweigh* or obes* or (excess* adj2 weigh*)) adj5 (clinic or clinics or office* or facility or facilities or practice*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (29)
12. 10 or 11 (361)
13. exp "Quality of Health Care"/ (6042072)
14. 5 and 13 (183311)
15. exp Ambulatory Care/ (49980)
16. exp Ambulatory Care Facilities/ (51539)
17. 15 or 16 (98681)
18. 14 and 17 (1003)
19. ((bariatr* or overweigh* or obes* or (excess* adj2 weigh*)) adj5 (clinic or clinics)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (668)
20. 6 or 13 (6062442)
21. 19 and 20 (498)
22. 18 or 21 (1459)
23. 12 or 22 (1808)
24. limit 23 to "all child (0 to 18 years)" (701)
25. limit 24 to english language (632)
26. limit 24 to abstracts (638)
27. 25 or 26 (684)

Filters/limits included research articles published in English in the last 10 years

CRITICALLY ANALYZE THE EVIDENCE

The literature search resulted in numerous studies reporting on multiple interventions. In order to simplify the review process, we grouped the evidence into five categories: (1) Family Therapy; (2) Multidisciplinary Care; (3) Combined Behavioral and Pharmacologic Interventions; and (4) Miscellaneous Treatment Programs, looking at the outcome on BMI, and (5) Dietary invention for asthma patients, looking at asthma-related quality of life.

1. Family Therapy: Six studies were found researching family therapy as an intervention in pediatric obesity treatment, one randomized control study and five non-randomized studies. The RCT (Wilfley 2017) randomized families to receive high or low doses of family-based therapy after 4-months of family-based behavioral weight loss treatment, compared to a control arm that received weight-control education. High had better outcomes than low (difference, −3.37; 95% CI, −6.15 to −0.59; d = −0.38; P = .02) and control (difference, −6.71; 95%CI, −9.57 to −3.84; d = −0.77; P < .001). A greater proportion of children in high (45 [82%]) vs low (34 [64%]) (difference, 18.00; 95%CI, 1.00-34.00; P = .03; number needed to treat = 5.56) and control (25 [48%]) (difference, 34.00; 95%CI, 16.00-51.00; P < .001; number needed to treat = 2.94) had clinically significant percentage overweight reductions. One non-randomized study (Nowicka 2007) focused on the influence of low-intensity family therapy with a minimum of four visits over a period of nine months. This intervention resulted in a mean decrease in BMI z-score of 0.12 (p = 0.0001) in participants. One cohort study (Maggio 2013) used an integrative approach with families including cognitive behavioral techniques and motivational interviewing that showed a decrease in BMI z-score mean: -0.18 +/= 0.40 in 49.5% of participants. A retrospective controlled study (Daneilsson 2016) offered both individual and family meetings that showed a 72% decline of 0.5 BMI SDS units. Another study (Holm 2011) integrated treatment regiments that were individualized and family-based with no time limits into a best-practice chronic care model. This study resulted in a BMI standard deviation score decrease of 0.23. Lastly, one article (Ewing 2009) studied the effects of training providers on weight loss interventions and brief motivational counseling skills in order to delivery family-based behavioral interventions. This intervention was statistically significant after five months of implementation with the average weight loss mean of 2.64 (1.5 SD).
   Quality of Evidence: Low

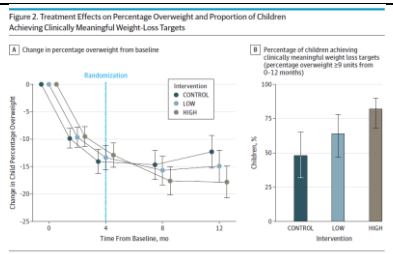
1. Multidisciplinary Care: We reviewed four retrospective studies assessing the impact of multidisciplinary care on obesity outcomes. One retrospective study (Skelton 2008) used a multidisciplinary team utilizing medical management, nutrition education, behavioral intervention, and physical activity interventions to treat patients. There was an overall increase in absolute BMI, but a small, yet significant decrease in BMI z-score (mean -0.013 +/= 0.16). The second retrospective study (Walsh 2014) included approximately six hours of care over 12 months from a medical provider, psychologist, registered dietitian nutritionist, exercise physiologist, and nurse. Nearly all returning patients stabilized or improved their BMI (90% of those who participated <6 months, 97% of those who participated 6 to <12 months, and 92% of those who participated >/= 12 months). Another study (Kirk 2015) was conduct to evaluate two dietary approaches and extend of registered dietitians (RD) involvement on outcomes of obese youth in comprehensive weight management. The study found that each additional RD visit was associated with a 28% increased odds of success. The last study (Emerson 2017) included was a retrospective chart review comparing a change in BMI in patients in multidisciplinary program that included a graded exercise test. The patients who participated in the exercise test had an average BMI of 30.7 preintervention and 28.7 postintervention.
   Quality of Evidence: Low

2. Pharmacologic and Behavioral Interventions: Two systematic reviews studied the effects of combined pharmacologic and behavioral interventions. One systematic review (Oude Luttikhuis 2009) identified three types of medication in drug trials in adolescents >/= 12 years old using metformin, orlistat, and siburtramine. The analysis showed a mean BMI decrease of -1.66 [-1.89, -1.43] between studies. The second systematic review (Whitlock 2209) identified seven trials (all fair- or good-quality randomized, controlled trails) for which short-term, weight effects of either sibutramine or orlistat plus behavioral counseling in adolescents aged 12 to 19 years were reported. Participants who received 10 to 15 mg/day of medication plus a behavioral intervention decreased their BMI by 2.9 kg/m2 after 12 months, compared with a BMI reduction of 0.3 kg/m2 among trial participants who received a behavioral intervention plus placebo.
   Quality of Evidence: Moderate

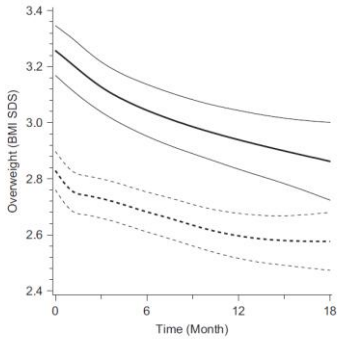
3. Miscellaneous Treatment Programs: We reviewed four RCTs and one non-randomized study evaluating the impact of miscellaneous treatment programs on obesity outcomes. One RCT (Boutelle 2013) assessed the impact of a guided self-help treatment program on participants BMI by delaying treatment in the control group. The participants in the immediate treatment arm decreased their BMI significantly more than did the delayed treatment arm (BMI group x time = -1.39. P .001). One RCT (Ford 2009) used a device known as the Mandometer to provide participants in the intervention group feedback during meals on slowing down their speed of eating and reducing total intake. Participants in the Mandometer group had significantly lower mean BMI SDS at 12 months compared with standard care (baseline adjusted mean difference 0.24, 95% confidence interval 0.11 to 0.36). The third RCT (Hughes 2008) included used family-centered counseling and behavioral strategies to modify diet, physical activity, and sedentary behavior. The intervention had no significant effect relative to standard care on BMI z score from baseline to 6 months and 12 months. The four RCT (Norman 2016) compared a stepped-down intervention versus enhanced usual care. Results indicated a clinically significant treatment effect for boys on BMI (P < 0.0001) but not girls. Lastly, we evaluated outcomes from one non-randomized pilot study based on the 5210 program that educated children and parents in separate programs about nutrition, obesity, and its long-term risks. Only 6 patients completed all steps in the program, but initial results showed that when the provider identified the issue of obesity and the child was assessed for readiness and integrated in the behavioral modification program, 63% of the group reduced their BMI.
   Quality of Evidence: Low

4. Dietary Intervention for Asthma Patients: One RCT (Luna 2014) was found looking at whether a dietary intervention would improve asthma-related quality of life (AR-QOL) in obese pubertal adolescents with asthma. Participants were allocated either to an interventional 28-week program of normoclaric diet based on normal requirements for height and meal planning or a non-intervention control group. The study showed that diet intervention was associated with a significant improvement in AR-QOL in relation to baseline (DELTA PAQLQ[S] scores) compared with controls, both in overall score ($p < 0.001$) and its subdomains (activity limitation, $p < 0.001$; symptoms, $p < 0.002$; emotional function, $p < 0.001$).

PICO Question: What are best practices for establishing a comprehensive obesity management program in the clinical setting (including physical therapy, social work, nutrition, etc.) for pediatric patients (< 21 years) to contribute to long-term weight maintenance?						Lower Quality Rating if: ☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)* ☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)* ☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)* Increase Quality Rating if: ☐ Large Effect ☐ Dose-response gradient
Modality: Family Therapy						
Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*	
Total # of Studies: 6 # of Systematic Reviews: 0 # of RCTs: 1 # of Non-Randomized Studies: 5 # of Diagnostic Studies: 0						
Wilfrey, D.E., et al., 2017, *JAMA Pediatrics*	To evaluate effects, following a 4-month family-based behavioral weight loss treatment (FBT), of 2 doses (HIGH or LOW) of a weight-control intervention (enhanced social facilitation maintenance (SFM+}) vs a weight-control education condition (CONTROL; matched for dose with LOW) on child anthropometrics , and to explore putative mediators of weight loss outcomes	RCT; Children (aged 7 – 11) years with overweight or obesity >/= (85th percentile for age and sex) and at least 1 parent with overweight of obesity (BMC >/= 25). Dyads entered family-based therapy (FBT) for 0-4 months and received 30-minute family sessions and 45-minute separate parent and child groups. Dyads were randomized at 4 months to HIGH, LOW, or CONTROL. HIGH was 32 weekly sessions and LOW was 16 every-other-week sessions. All information, handouts, and materials were provided to families in HIGH and LOW, but HIGH received additional opportunities to engage in and practice skills through more intervention contact. CONTROL was a weight management education intervention. Families received novel information on nutrition and exercise beyond what FBT provided and participated in hands-on activities, including cooking, stretching, and grocery store tours. Relative weight outcomes were assessed at months 0, 2, 4, 8, and 12.	241 parent-child dyads, 172 randomized after 4 months; 59 to HIGH, 56 to LOW, and 57 to CONTROL	Across conditions, for all relative weight measures, there was significant change during pre-randomization FBT from months 0 to 4 (all P < .001). The 3 conditions (HIGH, LOW, and CONTROL) attended a similar number of FBT sessions. As designed, participants in HIGH attended more maintenance sessions (mean [SD], 23.5 [7.8]) than LOW (12.5 [3.7]) or CONTROL (10.4 [3.9]) from months 4 to 12. **Following FBT, children in HIGH had superior reductions with a 3.37 decrease compared with LOW (95% CI, −6.15 to −0.59; d = −0.38; P = .02), and a 6.71 decrease compared with CONTROL (95%CI, −9.57 to −3.84; d = −0.77; P < .001).** Children in LOW showed intermediate reductions with a 3.34 decrease compared with children in CONTROL (95%CI, −6.21 to −0.47; d = −0.40; P= .02). HIGH had the largest proportion of children (n = 45 [82%]) who achieved greater than or equal to a 9-unit decrease in percentage overweight from months 0 to 12. Specifically, the proportion of children in HIGH was 34 percentage points higher compared with CONTROL (95% CI, 16 to 51; P < .001; NNT = 2.94), and 18 percentage points higher compared with LOW (95% CI, 1 to 34; P = .03; NNT = 5.56). There was a difference of 16 percentage points (95% CI, −3 to 35; P = .10; NNT = 6.25) between LOW and CONTROL. The results were similar for achievement of a BMI z score reduction of 0.25 or more from baseline.	Study Limitations = ☐ None ***RCTS*** ☒ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☒ Selective reporting of measures (e.g., no effect outcome)+++ ☒ Large losses to F/U ☐ Difference in important prognostic factors at baseline	

				 Figure 2. Treatment Effects on Percentage Overweight and Proportion of Children Achieving Clinically Meaningful Weight-Loss Targets A Change in percentage overweight from baseline B Percentage of children achieving clinically meaningful weight loss targets (percentage overweight ≥9 units from 0-12 months) Randomization Intervention CONTROL LOW HIGH Change in Child Percentage Overweight Time From Baseline, mo Children, % Intervention Table 3. Between-Group Difference in Percentage of Children Achieving Clinically Meaningful Weight Loss Target (Month 0 to Month 12)[a] Comparison / Percentage Point Difference (95% CI) / P Value / Number Needed to Treat HIGH vs CONTROL / 34 (16 to 51) / <.001 / 2.94 LOW vs CONTROL / 16 (−3 to 35) / .10 / 6.25 HIGH vs LOW / 18 (1 to 34) / .03 / 5.56		☐ Plausible confounders or other biases increase certainty of effect Quality (certainty) of evidence for studies as a whole: ☐ High ☐ Moderate ☒ Low ☐ Very Low
Daneilsson, P., et al., 2016, *Acta Peadiatrica*	To investigate long-term continuous behavioral childhood obesity treatment and factors of importance for treatment effect	Retrospective Controlled Study; A five-year study of children aged five to 13 years in obesity treatment treated at Sodertalje Hospital, Sweden, between January 2002 and October 2007. Children were divided into three groups depending on age at start of treatment. The clinic offered both individual meetings child and parent or family together and group activities for parents and children separately.	220 children met the inclusion criteria; The numbers of children in the three age groups were 33 (age 4–6 years), 85 (age 7–10) and 102 (age 11–13). As a comparison group, in total 369 obese children (45% girls, mean age 9.3 years, range 4.3– 13.9 years, mean BMI standard deviation score (SDS) 3.3 SD 0.6) were identified from 20 different outpatient clinics	After five years of treatment, the decrease in BMI SDS was significant in all age groups with the largest effect in age group 4-6 years. Compared to the comparison group (n = 369), the decline in BMI SDS was greater (p = 0.001). **After five years of treatment, 48% of the patients were cured from their obesity and 72% reached a decline of 0.5 BMI SDS units**. Age at start of treatment was the only factor affecting treatment efficacy.	Study Limitations = ☐ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☒ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	
Ewing, L.J., et al., 2009, *Clinical Pediatrics*	To study the effects of (a) training pediatric providers in the basics of pediatric weight management and the use of brief motivational counseling skills; (b) assess the	Observational Study; Training was implemented in each practice to (a) increase providers' knowledge regarding the assessment of obese children (measurement and importance of body mass index [BMI]) and about efficacious treatment models and (b) develop provider skills in the use of evidence-based motivational counseling techniques (used in their interactions with parents and children to assist them in taking	Two practices were included in study with 77 families enrolled total	Table 3. Weight and zBMI Change in Completer Group From Entry to Completion of the Study N[a,b] / Mean (SD) Weight (lb) Baseline / 37 / 131.10 (31.3) Visit 8 / 37 / 127.45 (31.9) Visit 11 (5 months after enrollment) / 33 / 128.26 (32.1) zBMI Baseline / 37 / 3.18 (1.4) Visit 8 / 37 / 3.07 (1.5) ZVisit 11 (5 months after enrollment) / 33 / 2.64 (1.5)[a] Note: BMI = body mass index; SD = standard deviation. a. $P = .001$. b. Although 37 children were defined as "completers" because they attended 6 of 8 initial sessions and 1 of 3 follow-up sessions, not all 37 were available for weight measurement at visit 11.	Study Limitations = ☐ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☒ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	

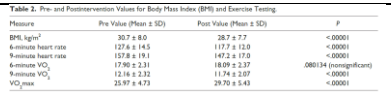
	feasibility and potential utility of offering family-based behavioral intervention; and (c) train professional staff to deliver interventions to assure sustainability	steps toward healthier nutritional and physical activity behaviors). To address the feasibility of offering an evidence-informed intervention in primary care, clinic offered an intervention that consisted of 8 weekly group sessions for referred children and at least 1 parent, followed by 3 monthly individual sessions. Nurses also were trained to deliver the manualized group intervention. In addition, each family met individually with an interventionist for 10 to 15 minutes to review progress, address specific challenges, and set individual goals for the subsequent week. The 3 monthly follow-up sessions occurred in the pediatric office. Each family met with the nurse educator for approximately 15 minutes to measure weight and discuss successes and challenges that the child and parent had experienced.		Average weight loss among completers was greatest at 8 weeks (3.65 lb), but the **change in BMI z scores (zBMI) was highly statistically significant at 5 months** (P < .001).		
Holm, J.C., et al., 2011, *International Journal of Pediatric Obesity*	To report results for a clinic-based structured treatment program for chronic childhood obesity	Prospective Study; Children and youths were invited to participate who were older than three and if their BMI was above the 90th percentile for sex and age. Children were seen quarterly, half-yearly, or annually for a 30-min appointment in outpatient clinics using a family-centered approach involving behavior-changing techniques. The patient was also seen by a dietician at the first appointment for one hour and later for 30 minutes. Patients were followed until the successfully reached their goal, which was defined as a BMI	617 children or youths; 325 girls and 292 boys	After 12 months, the mean BMI SDS decreased by 0.23 ($P < 0.0001$) in girls and by 0.32 ($P < 0.0001$) in boys. After one year, the retention rate was 90.2%, and 68.7% had reduced SMI SDS. After two years, the retention rate was 75% of which 62.5% had reduced BMI SDS. Boys lost more body weight than did girls ($P = 0.02$) but younger girls (< 11.6 years) lost more weight ($P = 0.005$) than older girls (> 11.6 years) although the weight loss was still significant among older girls ($P < 0.0001$).	Study Limitations = ☐ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☒ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	

		below the 75th percentile for sex and age or exited the program.		 Figure 1. Mean changes in BMI SDS with 95% confidence intervals in boys (top graph) and girls (lower graph) included in TCOCT protocol who were seen at two visits or more according to a generalized linear mixed model incorporating all visits from all patients. BMI SDS, body mass index standard deviation score.		
Maggio, A., 2013, *BMC Pediatrics*	To determine changes in BMI after individual family-based obesity intervention with a pediatrician in a specialized obesity center for child and adolescent	Cohort Study; Patients had at least two visits at the Pediatric Obesity Care Center of the Geneva University Hospitals between January 2008 and December 2010. Pediatricians used an integrative approach with families that included cognitive behavioral techniques (psycho-education, behavioral awareness, behavioral changes by small objectives and stimulus control) and motivational interviewing. If needed, patients were referred to psychologists.	283 patients; 145 girls and 138 boys. Mean BMI and BMI z-score were 26.4+/=4.7kgm -2 and 2.7+/=0.9	Mean follow-up duration was 11.4 ± 9.8 months. **The decrease in BMI z-score (mean: -0.18 ± 0.40; p < .001) was significant for 49.5% of them**. It was dependent of age, BMI at baseline (better in youngest and higher BMI) and the total number of visits (p = .025). Additional psychological intervention was associated with reduced BMI z-score in children aged 8 to 11 years (-0.29 ± 0.62 vs. -0.12 ± 0.28; t = 2.05, p = .048)	Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	
Nowicka, P., 2007, *International Journal of Pediatric Obesity*	To study the influence of low-intensity solution-focused family therapy with obese and extremely obese pediatric subjects on BMI, z-scores, and self esteem	Prospective Study; Families received solution-focused family therapy provided by a multidisciplinary team. During the first visit, a family meets the entire multidisciplinary treatment team, which enables the family to discuss all aspects of lifestyle changes, including nutrition, physical activity, behavior, and pediatric medication. The team also helped the family establish the treatment goal by using an	54 obese children, aged 6-17 years.	81% of the children (n=44, mean age 11.9 years, mean BMI z-score 3.67, range 2.46-5-48) and their parents participated in follow-up. 11 children were treated for 6 – 12 months, and 33 for more than 12 months. On average, the families received 3.8 family therapy sessions. **Intervention resulted in a mean decrease in BMI z-score of 0.12 (p = 0.0001).** Self-esteem on the global scale improved after intervention (p = 0.002), and also on sub-scales, depicting physical characteristics (p<0.001), physiologic well-being (p =	Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	

		interdisciplinary approach that delivers a consistent message to the family. Self-esteem was assessed with a validated questionnaire. Parents completed "The Family Climate Scale" assessing family dynamics.		0.026), and relations with others (p = 0.002).		

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix A.

PICO Question: What are best practices for establishing a comprehensive obesity management program in the clinical setting (including physical therapy, social work, nutrition, etc.) for pediatric patients (< 21 years) to contribute to long-term weight maintenance?						Lower Quality Rating if:
Modality: Multidisciplinary Care						☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*
Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*	☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*
Total # of Studies: 4 # of Systematic Reviews: 0 # of RCTs: 0 # of Non-Randomized Studies: 4 # of Diagnostic Studies: 0						☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*
Skelton, J.A., 2008, *Obesity Journal*	To determine whether a multidisciplinary pediatric weight management program effectively improves BMI, BMI z-score, and cardiovascular risk factors (CVRFs) in high-risk population	A retrospective study; Chart reviews were performed on children seen in the NEW Kids Program at the Children's Hospital of Wisconsin, a family-based clinic that treats pediatric obesity using medical management, nutrition education, behavioral intervention, and physical activity.	66 patients; Inclusion criteria were program participation for ≥9 months and >4 visits.	**There was an overall increase in absolute BMI, but a small, yet significant decrease in BMI z-score (mean –0.03 ± 0.16; P < 0.05).** There were significant pre-group to post-group improvements in total cholesterol, low-density lipoprotein, and triglycerides levels	Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	☐ Publication Bias *(e.g. pharmaceutical company sponsors*
Walsh, S.M., 2014, *Nutrition in Clinical Practice*	To describe the design and initial quality-related outcomes of the Strong4Life multidisciplinary pediatric obesity treatment program along with challenges and solutions implemented	Retrospective Study; The Strong4Life Clinic obesity program provides children with the medical care, as well as the behavior change guidance and support needed to reverse their obesity and/or minimize the related health risks. The program includes approximately 6 hours of care over 12 months from a medical provider, psychologist, registered dietitian nutritionist, exercise physiologist, and nurse.	781 high-risk patients	66% returned for at least 1 visit. **Nearly all returning Strong4Life patients stabilized or improved their BMI** (90% of those who participated <6 months, 97% of those who participated 6 to <12 months, and 92% of those who participated >/=12 months).	Study Limitations = ☐ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☒ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	

	over the first 2 years.					*study on effectiveness of drug, only small, positive studies found)*
Emerson, M., et al., 2017, *Clinical Pediatrics*	To compare a change in BMI in patients in multidisciplinary program with graded exercise test ordered before and after a 16-week dietary and exercise intervention	Retrospective chart review; Exercise classes were offered including physical activity and typically consisted of 5 to 10 minutes stretching, exercises, and warm-up, 15 to 20 minutes of active games, 10 minutes of resistance training, 10 minutes of cardiovascular exercise, 10 minutes of active games, and 5 minutes of stretching exercises and cool-down. Participant's BMI was followed for 8 years through chart review.	299 youth with obesity aged 7 to 18 years		Study Limitations = ☐ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☒ Differences in important prognostic factors at baseline	<u>Increase Quality Rating if:</u> ☐ Large Effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect Quality (certainty) of evidence for studies as a whole: ☐ High ☐ Moderate ☒ Low ☐ Very Low
Kirk, S., et al, 2015, *Child Obes*	To evaluate two dietary approaches and extend of registered dietitian (RD) involvement on outcomes of obese youth participating in comprehensive weight management (CWM)	Retrospective Study; Review of CWM patients was conducted before and after redesign of the nutrition component. The earlier clinical model (CM1) introduced a portion-controlled diet at an RD visit after the initial medical visit, whereas the later clinical model (CM2) introduced a reduced glycemic load diet at the initial medical visit. CWM patients were included if they had at least one RD visit and an initial and 3- to 6-month medical follow-up visit during CM1 or CM2. Differences between CM1 and CM2 groups regarding changes in BMI and programmatic success (BMI change </=0) were evaluated.	92 participants; 41 in CM1 and 51 in CM2	Median BMI change during follow-up did not differ between CM1 (n=41) and CM2 (n=51) groups (p=0.41). In a multiple logistic regression model combining study groups, each additional RD visit was associated with a 28% increased odds of success (odds ratio [95% confidence interval]: 1.28 [1.00, 1.64]; p=0.05). The probability of success exceeded 78% with >/=1 RD visit/month versus 43% with minimal RD exposure.	Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	

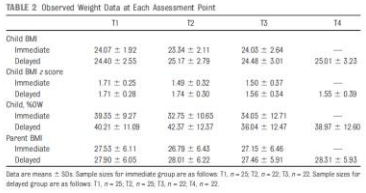
The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix A.

PICO Question: What are best practices for establishing a comprehensive obesity management program in the clinical setting (including physical therapy, social work, nutrition, etc.) for pediatric patients (< 21 years) to contribute to long-term weight maintenance?	<u>Lower Quality Rating if:</u> ☐ Studies inconsistent (*wide variation of*
Modality: Combined Pharmacologic and Behavioral Interventions	

Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*	*treatment effect across studies, populations, interventions, or outcomes varied)* ☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)* ☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)* <u>Increase Quality Rating if:</u> ☐ Large Effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect
Total # of Studies: 2 # of Systematic Reviews: 2 # of RCTs: 0 # of Non-Randomized Studies: 0 # of Diagnostic Studies: 0						
Oude Luttikhuis, H., et al., 2009, *Cochrane Database for Systematic Reviews*	To assess the efficacy of lifestyle, drug and surgical interventions for treating obesity in childhood	Systematic Review with meta-analysis	64 RCTs, 5,230 participants	Meta-analyses showed a mean BMI decrease of -1.66 [-1.89, -1.43] between studies.	Study Limitations = ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised or studies were of low quality ☒ Methods and/or results were inconsistent across studies	
Whitlock, E.P., et al., 2009, *Pediatrics*	To examine the benefits and harms of behavioral and pharmacologic weight-management interventions for overweight and obese children and adolescents	Systematic Review with meta-analysis	Evaluated 13 behavioral intervention trials conducted in 1,258 overweight or obese children and adolescents aged 4 to 18 years. Article also evaluated 7 trials that combined pharmacologic treatments (sibutramine or orlistat) with behavioral interventions in a total of 1,294 obese adolescents aged 12 to 18 years.	Behavioral Interventions: Found that comprehensive medium- to high-intensity behavioral interventions for obese children and adolescents (>95th to 97th percentile for age and gender) aged >/= 6 years can effectively produce short-term improvements in weight. The weight change associated with these interventions was generally modest (1.9-3.3 kg/m2 difference between groups in mean change in BMI after 6-12 months). Combined Pharmacologic and Behavioral Interventions: Pharmacologic adjuncts to behavioral interventions have been studied only in obese adolescents aged 12 to 18 years who met adult criteria for class II obesity (mean BMI of 35-40 kg/m2 at trial entry); these adjuncts provide superior benefits compared with behaviorally based treatment alone. **Participants who received 10 to 15 mg/day of medication plus a behavioral intervention decreased their BMI by 2.9 kg/m2 after 12 months, compared with a BMI reduction of 0.3 kg/m2 among trail**	Study Limitations = ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised or studies were of low quality ☐ Methods and/or results were inconsistent across studies	

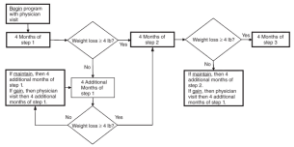
				participants who received a behavioral intervention plus placebo.		Quality (certainty) of evidence for studies as a whole: ☐ High ☒ Moderate ☐ Low ☐ Very Low

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix A.

PICO Question: What are best practices for establishing a comprehensive obesity management program in the clinical setting (including physical therapy, social work, nutrition, etc.) for pediatric patients (< 21 years) to contribute to long-term weight maintenance?						Lower Quality Rating if:
Modality: Miscellaneous Treatment Program						☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)* ☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)* ☐ Publication Bias
Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*	
Total # of Studies: 5 # of Systematic Reviews: 0 # of RCTs: 3 # of Non-Randomized Studies: 2 # of Diagnostic Studies: 0						
Boutelle, K., et al., 2013, *Pediatrics*	To evaluate the efficacy of a guided self-help treatment of pediatric obesity (GSH-PO) compared with a delayed treatment control and to evaluate the impact of GSH-PO 6-months posttreatment	RCT; Overweight or obese 8- to 12-year-old children and their parents were randomly assigned to immediate treatment or delayed treatment. The GSH-PO includes 12 visits over 5 months and addresses key components included in more intensive clinic-based programs. Children and parents in the immediate treatment arm were assessed at time 1 (T1), participated in GSH-PO between T1 and T2, and completed their 6-month posttreatment assessment at T3. Children and parents in the delayed treatment arm were assessed at T1, participated in GSH-PO between T2 and T3, and completed their 6-month posttreatment assessment at T4.The GSH-PO intervention included 12 visits over 5 months. The treatment frequency and	50 children	**Children in the immediate treatment GSH-PO arm decreased their BMI significantly more than did the delayed treatment arm (BMI group x time = -1.39; P .001).** Similar results were found for BMI z score and %OW. At the 6-month posttreatment assessment, changes resulting from GSH-PO were maintained for BMI z score and %OW but not BMI (BMI time effect = -0.06, not significant; BMI z score time effect = -0.10, P = 0.001; %OW time effect = -4.86, P = 0.05). TABLE 2 Observed Weight Data at Each Assessment Point  T1 T2 T3 T4 Child BMI Immediate 24.07 ± 1.92 25.34 ± 2.11 24.03 ± 2.64 — Delayed 24.40 ± 2.55 25.17 ± 2.79 24.48 ± 3.01 25.01 ± 3.23 Child BMI z score Immediate 1.71 ± 0.25 1.49 ± 0.32 1.50 ± 0.37 — Delayed 1.71 ± 0.28 1.74 ± 0.30 1.56 ± 0.34 1.55 ± 0.39 Child, %OW Immediate 39.55 ± 9.27 32.75 ± 10.65 34.05 ± 12.71 — Delayed 40.21 ± 11.09 42.37 ± 12.37 38.04 ± 12.47 38.97 ± 12.60 Parent BMI Immediate 27.53 ± 6.11 26.79 ± 6.43 27.15 ± 6.46 — Delayed 27.90 ± 6.05 28.01 ± 6.22 27.46 ± 5.91 28.31 ± 5.93 Data are means ± SDs. Sample sizes for immediate group are as follows: T1, $n = 25$; T2, $n = 22$; T3, $n = 22$. Sample sizes for delayed group are as follows: T1, $n = 25$; T2, $n = 25$; T3, $n = 22$; T4, $n = 22$.	Study Limitations = ☐ None ***RCTS*** ☒ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome)+++ ☐ Large losses to F/U ☐ Difference in important prognostic factors at baseline	

		time for visits (every other week for 20 minutes) was chosen to develop a method that could be used in primary care clinics. Families received a parent manual, a child manual, and an activities manual. The activities manual was designed to provide activities and games that parents and children could do together to enhance program learning at home. The parent, child, and activity manuals focused on the same topics each week, with the exception of parenting skills, and the information in the child manuals was provided in age appropriate language.				*(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)* Increase Quality Rating if: ☐ Large Effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect
Ford, A.L., 2009, *BMJ*	To determine whether modifying eating behavior with use of a feedback device facilitates weight loss in obese adolescents	RCT; This study was conducted at a children's hospital in England. Participants were new patients referred to the obesity clinic and were divided between intervention group and standard care group. The Intervention group, known as the Mandometer group because of the device provided that gave participants real time during meals on slowing down their speed of eating and reducing total intake. Mandometer group also received sessions once a week for six weeks with a research nurse. From week six to 12, the research nurse telephoned the Mandometer group every second week to offer support and encouragement. Participants were given four	106 newly referred obese people aged 9 – 17; 54 allocated to the Mandometer group and 52 allocated to the standard care group	**Participants in the Mandometer group had significantly lower mean BMI SDS at 12 months compared with standard care (baseline adjusted mean difference 0.24, 95% confidence interval 0.11 to 0.36).** Similar results were obtained when analyses included only the 91 who attended per protocol (baseline adjusted mean difference 0.27, 0.14 to 0.41; P<0.001), with the difference maintained at 18 months (0.27, 0.11 to 0.43; P=0.001) (n=87). The mean meal size in the Mandometer group fell by 45 g (7 to 84 g). Mean body fat SDS adjusted for baseline levels was significantly lower at 12 months (0.24, 0.10 to 0.39; P=0.001). Those in the Mandometer group also had greater improvement in concentration of high density lipoprotein cholesterol (P=0.043). Conclusions Retraining eating behaviour with a feedback device is a useful adjunct to standard lifestyle modification in treating obesity among adolescents.	Study Limitations = ☐ None ***RCTS*** ☐ Lack of blinding ☒ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☐ Large losses to F/U ☐ Difference in important prognostic factors at baseline	Quality (certainty) of evidence for studies as a whole: ☐ High ☐ Moderate ☒ Low ☐ Very Low

		dietetic consultations every four months.				
Hughes, A.R., et al., 2008, *Pediatrics*	To determine whether a generalizable best-practice individualized behavioral intervention reduced BMI z score relative to standard dietetic care among overweight children	RCT; Participants were randomly assigned to a best practice behavioral program (intervention) or standard care (control). The intervention used family-centered counseling and behavioral strategies to modify diet, physical activity, and sedentary behavior. BMI z score, weight, objectively measured physical activity and sedentary behavior, fat distribution, quality of life, and height z score were recorded at baseline and at 6 and 12 months TABLE 1 Comparison of the Best-Practice Individualized Behavioral Intervention With Standard Dietetic Care Parameter / Standard Care / Intervention No. of appointments / 3–4 / 8 Appointment style / Dietitian centered / Family centered Duration of treatment / 1.5 h over 6–10 mo / 5 h over 6 mo Diet / General healthy eating advice / Modified traffic light diet approach Physical activity / General advice given / Aim to increase to 1 h/d Sedentary behavior / Not targeted / Aim to reduce to <2 h/d Motivation explored / Not explored / Importance score and decisional balance chart Goals / Set by dietitian / Set by child Lifestyle self-monitoring / Not used / Used throughout program	134 overweight children; 59 boys and 75 girls with BMI >/= 98th percentile	The intervention had no significant effect relative to standard care on BMI z score from baseline to 6 months and 12 months. BMI z score decreased significantly in both groups from baseline to 6 and 12 months. For those compiled with treatment, there was a significantly smaller weight increase in those in the intervention group compared with control subjects from baseline to 6 months. There were significant between-group differences in favor of the intervention for changes in total physical activity, percentage of time spent in sedentary behavior, and light-intensity physical activity. TABLE 2 Baseline Characteristics of Study Participants According to Group Variable / Control Group (n = 65) / Intervention Group (n = 69) Age, mean (SD), y / 8.5 (1.9) / 9.1 (1.7) Male/female / 29/36 / 30/39 Maternal BMI, median (IQR), kg/m²* / 30.0 (25.2 to 35.8) / 28.0 (24.2 to 32.8) Paternal BMI, median (IQR), kg/m²* / 27.1 (24.7 to 31.7) / 26.1 (23.7 to 31.5) Socioeconomic status Nondeprived (1–4), n (%) / 30 (46.2) / 28 (40.6) Deprived (5–7), n (%) / 35 (53.8) / 41 (59.4) BMI z score, median (IQR) / 3.3 (2.8 to 3.6) / 3.2 (2.7 to 3.6) Weight, median (IQR), kg / 49.0 (41.2 to 61.7) / 52.6 (43.8 to 61.2) Waist circumference z score, median (IQR) / 3.3 (2.9 to 3.7) / 3.3 (2.9 to 3.6) Height z score, median (IQR) / 1.07 (−0.90 to 3.54) / 0.74 (−2.04 to 4.13) Total activity, median (IQR), cpm / 646 (526 to 821) / 649 (508 to 749) Monitored time, median (IQR), % /	Study Limitations = ☐ None ***RCTS*** ☐ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☒ Large losses to F/U ☐ Difference in important prognostic factors at baseline	
Norman, G., et al., 2016, *Pediatric Obesity*	To compare a stepped-down weight loss intervention versus enhanced usual care (EUC)	RCT; The goal of the stepped-down care model for the intervention arm was for adolescents to lose at least 4 lb every 4 months. If participant achieved 4-lb weight loss, the participant was "stepped-down" to the next lower level of reduced intensity. Stepped-down intervention was delivered through clinician and health educator counseling (in-person and by phone) and mailed	106 participants	Results indicated a clinically significant treatment effect for boys on BMI (P < 0.001) but not girls. Of the 13 (12%) adolescents who lost at least 5% of their body weight after 12 months of treatment, 9 (69%) of them were boys, with 7 of them in the SDC group compared with 2 in the EUC (P = 0.04). Treatment effects were not observed on blood pressure, plasma glucose, cholesterol (total or LDL), or triglycerides in girls or boys (Table 3). However, girls in the EUC group had a significantly greater decrease in LDL	Study Limitations = ☐ None ***RCTS*** ☒ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☒ Large losses to F/U	

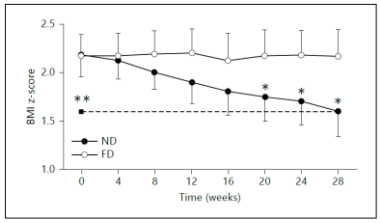
		content. The intervention consisted of four-month 'steps' beginning with the most intensive contact followed by reduced contact if treatment goals were met. The EUC group received an initial physician visit, one session with health counselor, and monthly mailed materials. BMI was measured at baseline, 4,8, and 12 months. 		cholesterol than girls in the SDC group, 99.4–80.9 vs. 94.1–86.1 (P = 0.04).. Only 13% of intervention participants succeeded in stepping down from step 1 to step 2 or step 3.	☐ Difference in important prognostic factors at baseline	
Kwapiszewski, R.M., 2011, *Clinical Pediatrics*	To study an innovative approach to addressing the issue of childhood obesity that starts with the primary care physician and involves group education with peers.	During a 10 month period, children diagnosed as obese or at risk for obesity were enrolled in a 4-step program. Pilot program patient BMI reduction results were compared to a control group that received standard care. The pilot program included an initial visit that established the diagnosis and assessed contributing or coexisting conditions. The second visit the family met a dietician who discussed nutrition, the 5-2-1-0 program, and to try new foods and recipes. The parents were also educated in a separate program about nutrition, obesity, and its long-term risks. On the third visit, the parent and child met with the primary provider to review the comorbid conditions and their appropriate management. The discussion included follow-up on any laboratory tests and counseling, as well as continued tracking of	68 patients in pilot program and 56 in control group	Table 2. Percentage Change in Body Mass Index (BMI) Relative to Pilot Program Start -312 Days -208 Days -104 Days Program Start 104 Days 208 Days Control group (n = 56) -1.33 -1.12 -0.08 0 -0.16 0.48 Completed at least 1 step (n = 68) -2.28 -1.87 -1.41 0 -0.12 -0.08 Completed 4 steps (n = 6) -2.28 -0.10 -0.25 0 -0.03 -0.43 Only 6 patients completed all 4 steps in the pilot program. **The initial results showed that when the provider identified the issue of obesity and the child was assessed for readiness and integrated in the behavioral modification program, 63% of the group reduced their BMI.**	Study Limitations = ☐ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☒ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☒ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline	

		the BMI and other vital signs. The fourth visit introduced exercise and physical activity.				

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix A.

PICO Question: What are best practices for establishing a comprehensive pediatric obesity management program (including physical therapy, social work, nutrition, subspecialty services, etc.) to contribute to long-term weight maintenance and provide treatment for associated co-morbidities (Type 2 DM, hyperlipidemia, obstructive sleep apnea, hypertension)?

Outcome: Asthma-related quality of life

Author/Date	*Purpose of Study*	*Study Design & Methods*	*Sample*	*Outcomes*	*Design Limitations*
Total # of Studies: 1 # of RCTs: 1					
Luna, Pech., J.A., 2014, *International Archives of Allergy & Immunology*	To evaluate whether a program of supervised ND would improve asthma-related quality of life (AR-QOL), specifically in obese pubertal adolescents with asthma.	RCT; Participants were allocated either to an interventional 28-week program of normoclaric diet based on normal requirements for height and meal planning or a non-intervention control group. Asthma-related quality of life (AR-QOL, assess by the Standardized Pediatric Asthma Quality of Life Questionnaire) and clinical indicators of asthma control were measured before and after intervention period	51 pubertal adolescents; 26 in intervention group and 25 in control group	Diet intervention was associated with a significant improvement in AR-QOL in relation to baseline (DELTA PAQLQ[S] scores) compared with controls, both in overall score ($p < 0.001$) and its subdomains (activity limitation, $p < 0.001$; symptoms, $p < 0.002$; emotional function, $p < 0.001$). The group with normocaloric diet observed a significant decrease in body mass index z-score, which correlated positively with the improvement in AR-QOL (Spearman's $r = 0.51$, $p < 0.01$), in addition to have significantly fewer events of acute attacks of asthma and nighttime awakenings, plus a non-significant reduction in the use of inhaled corticosteroids. No significant changes were observed in the pulmonary function tests. 	Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up ☐ Differences in important prognostic factors at baseline

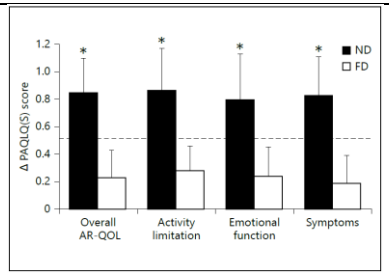
Lower Quality Rating if:

☐ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

						Increase Quality Rating if: ☐ Large Effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect Quality (certainty) of evidence for studies as a whole: ☐ High ☐ Moderate ☒ Low ☐ Very Low

Guideline Recommendations:

The **U.S. Preventive Services Task Force (USPTF) recommends** clinicians screen children aged 6 years and older for obesity and offer them or refer them to comprehensive, intensive behavioral intervention to promote improvement in weight status (B recommendation).

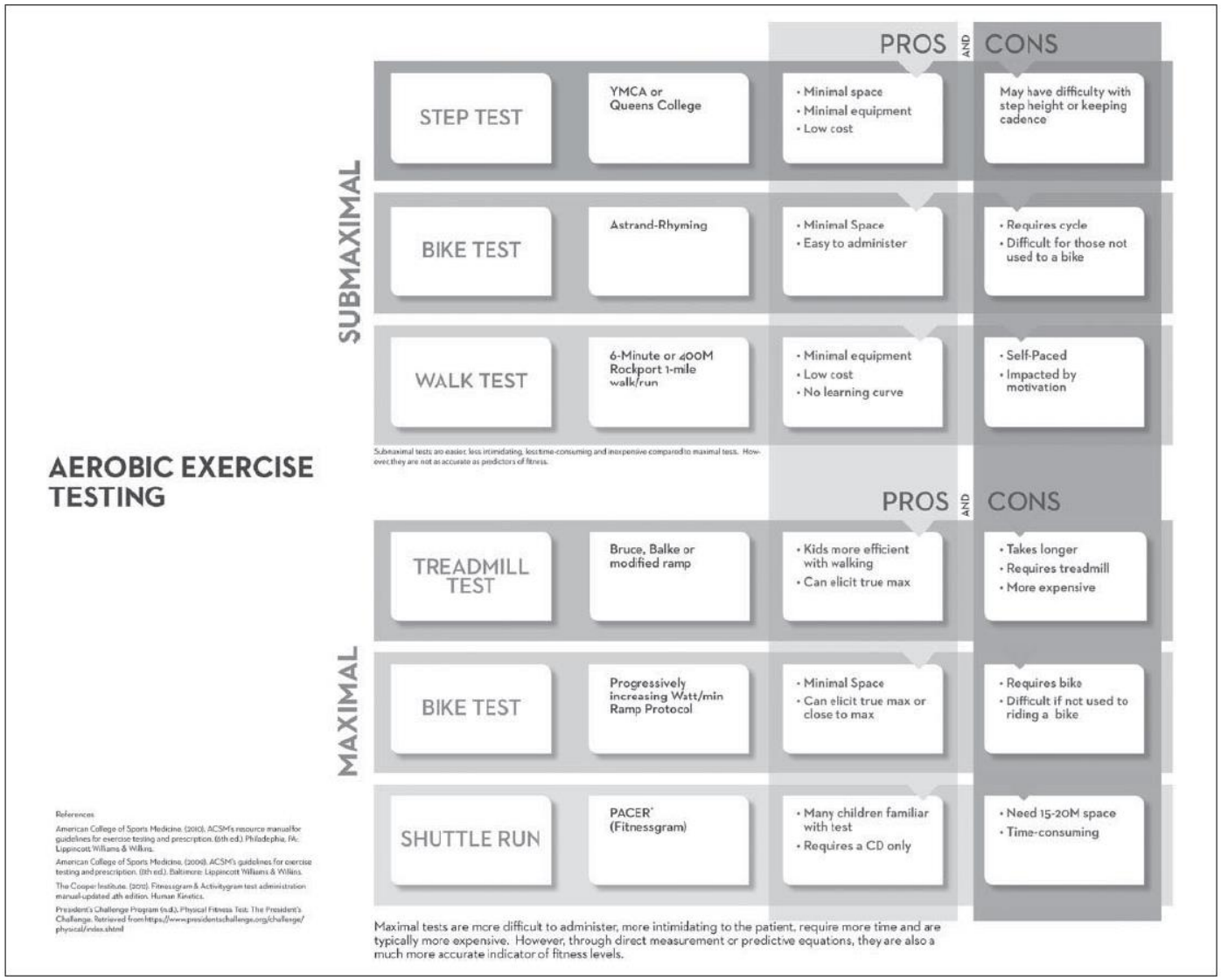
- Screening Tests: Body mass index measurement is the recommended screening test for obesity. (Level of evidence for recommendation not provided)
- Screening interval: The USPSTF found no evidence regarding appropriate screening intervals for obesity in children and adolescents. (Level of evidence for recommendation not provided)
- Treatment and Implementation: The USPSTF found that comprehensive, intensive behavioral interventions with a total of 26 contact hours or more over a period of 2 to 12 months resulted in weight loss. (Level of evidence for recommendation not provided)
    - Behavioral interventions varied but frequently included sessions targeting both the parent and child (separately, together, or both); offered individual sessions (both family and group); provided information about healthy eating, safe exercising, and reading food labels; encouraged

the use of stimulus control (eg, limiting access to tempting foods and limiting screen time), goal setting, self-monitoring, contingent rewards, and problem solving; and included supervised physical activity sessions.

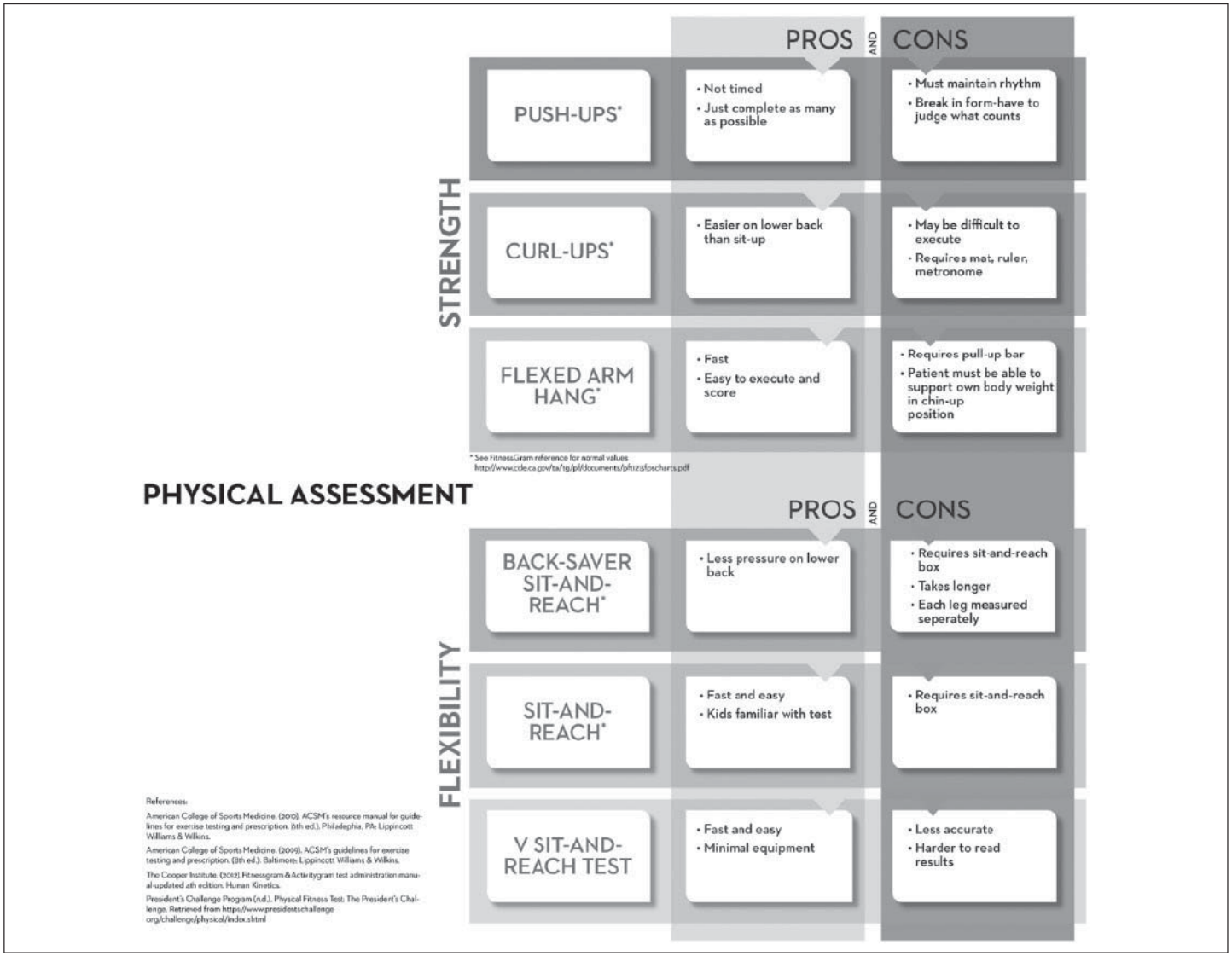
- Intensive interventions involving 52 or more contact hours rarely took place in primary care settings but rather in settings in which primary care clinicians could refer patients. These types of interventions were often delivered by multidisciplinary teams, including pediatricians, exercise physiologists or physical therapists, dietitians or diet assistants, psychologists or social workers, or other behavioral specialists.
- The USPSTF encourages clinicians to promote behavioral interventions as the primary effective intervention for weight loss in children and adolescents.

FOCUS on a Fitter Future (FFF) developed consensus statements on outcomes measurements and quality improvement for pediatric weight management programs which are as listed below:

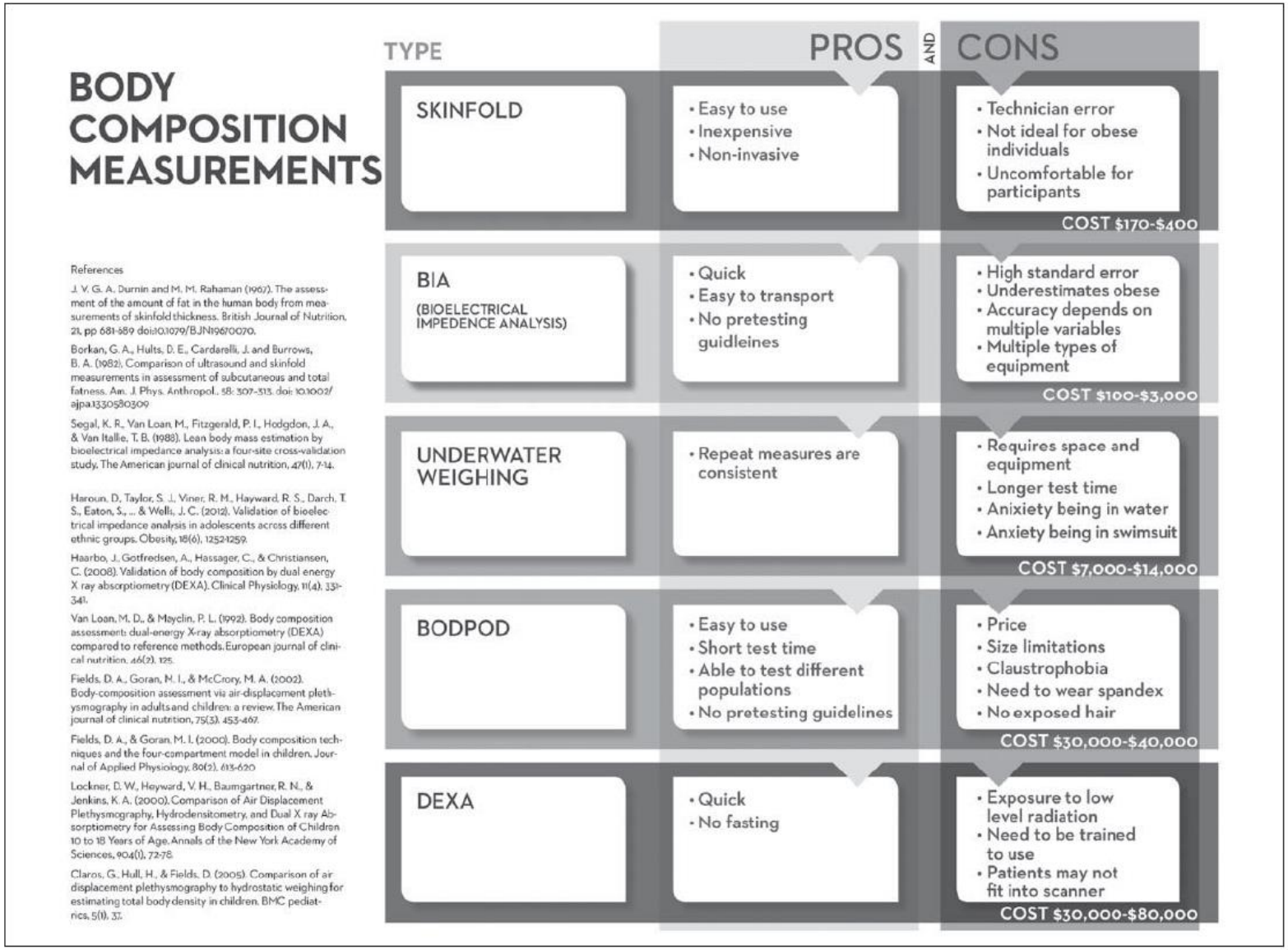
Aerobic fitness testing, as well as assessment of strength and flexibility, can be a valuable tool for determining a patient's initial capabilities and tracking improvements over the course of a program. These assessments help clinicians determine appropriate submaximal work rates so that physical activity (PA) recommendations can include individualized physical activities and intensities. At minimum, these measures should be performed at the beginning of the program to help guide initial PA recommendations, and again at the end of treatment to assess patient progress.



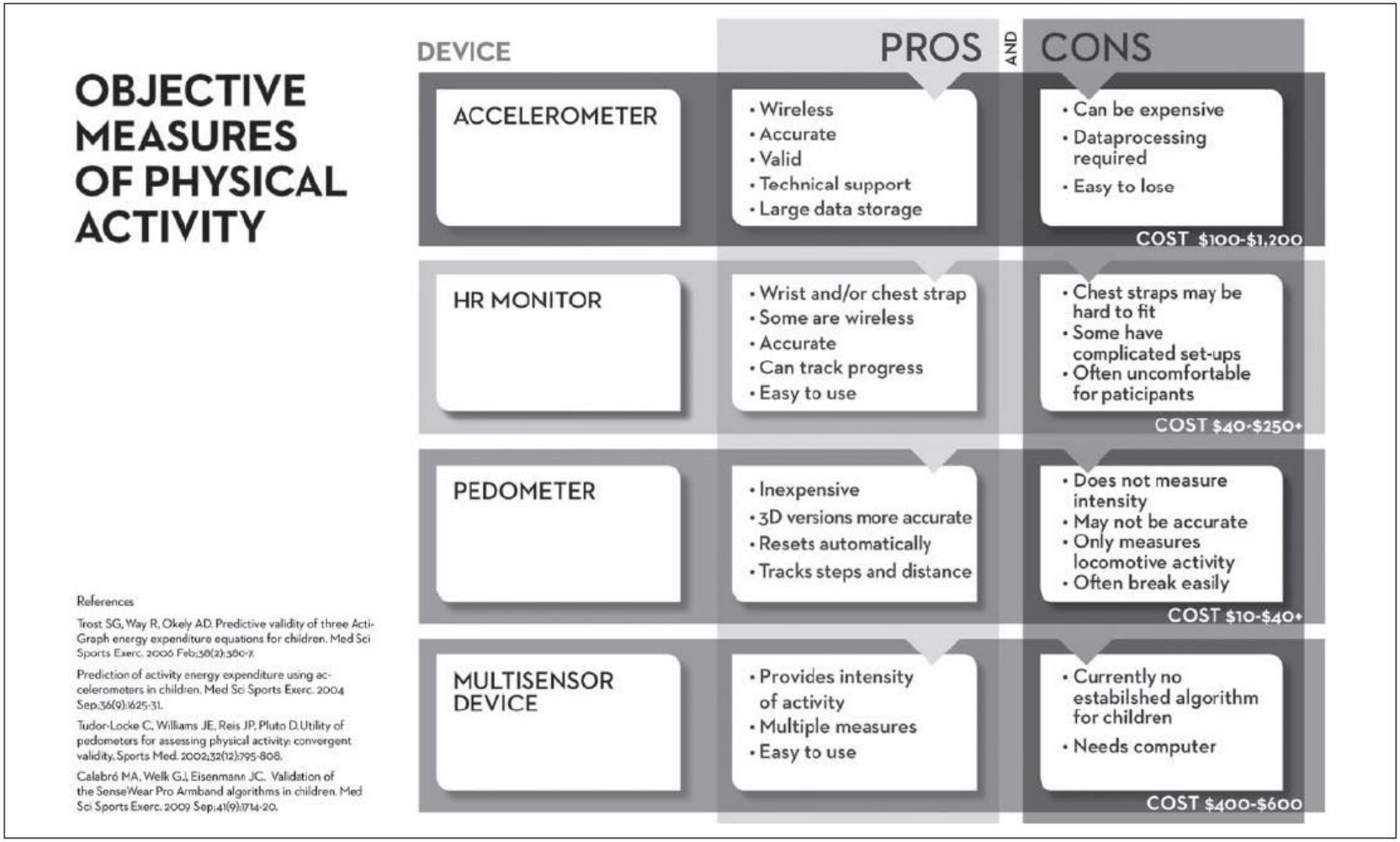
The frequency of physical activity assessment may vary depending on program resources and objectives, but such testing should be administered at minimum before and after treatment to help guide behavior change recommendations and to track participant changes. In general, PA assessment should include at least 7 days of monitoring during waking hours to account for variation across weekdays and weekends.



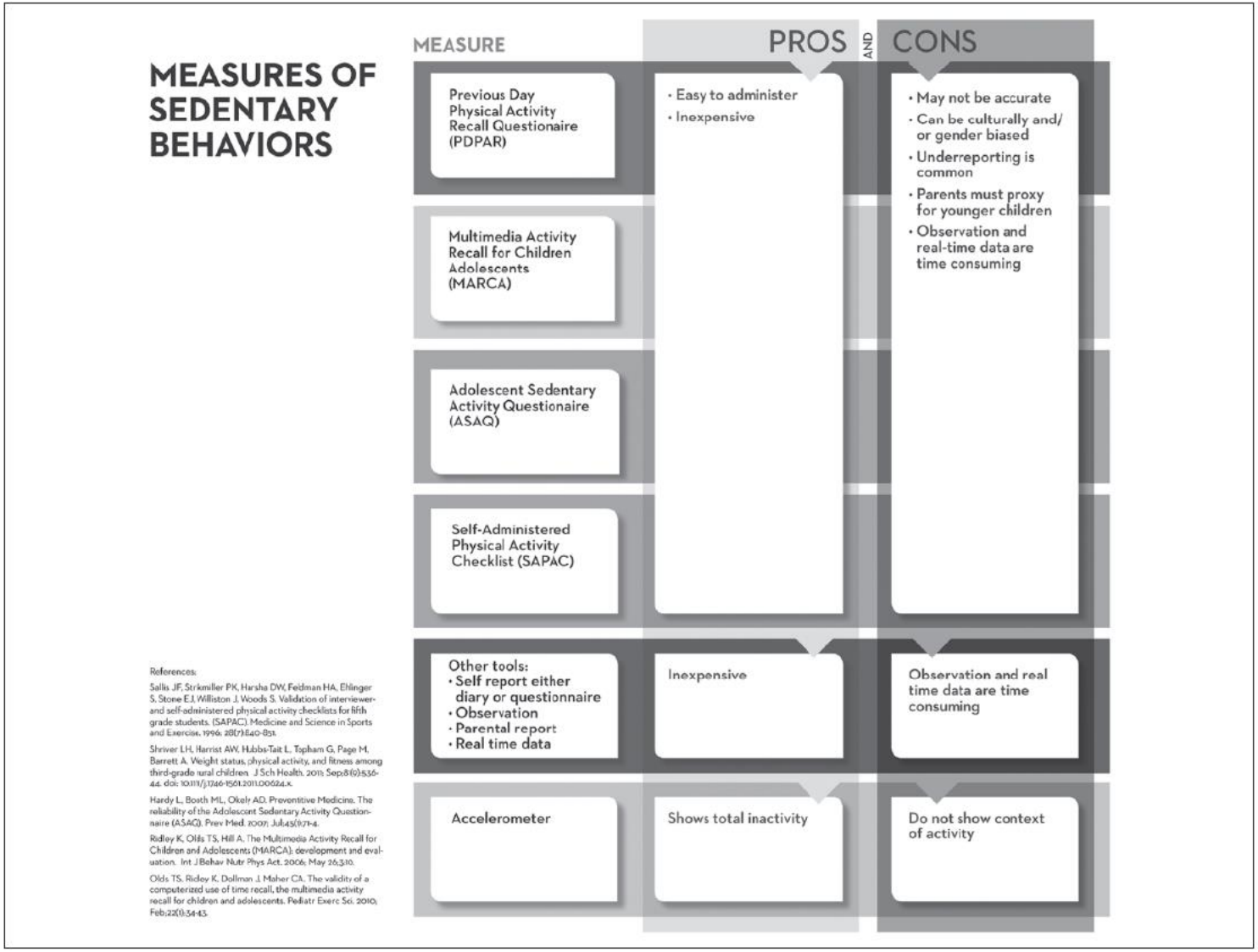
There are many options to access body composition, including bioelectrical impedance analysis, air displacement plethysmography, skinfold measurements, and DEXA scans. Factors such as ease of use, cost, and accuracy must be considered when choosing the best method for a weight management program.



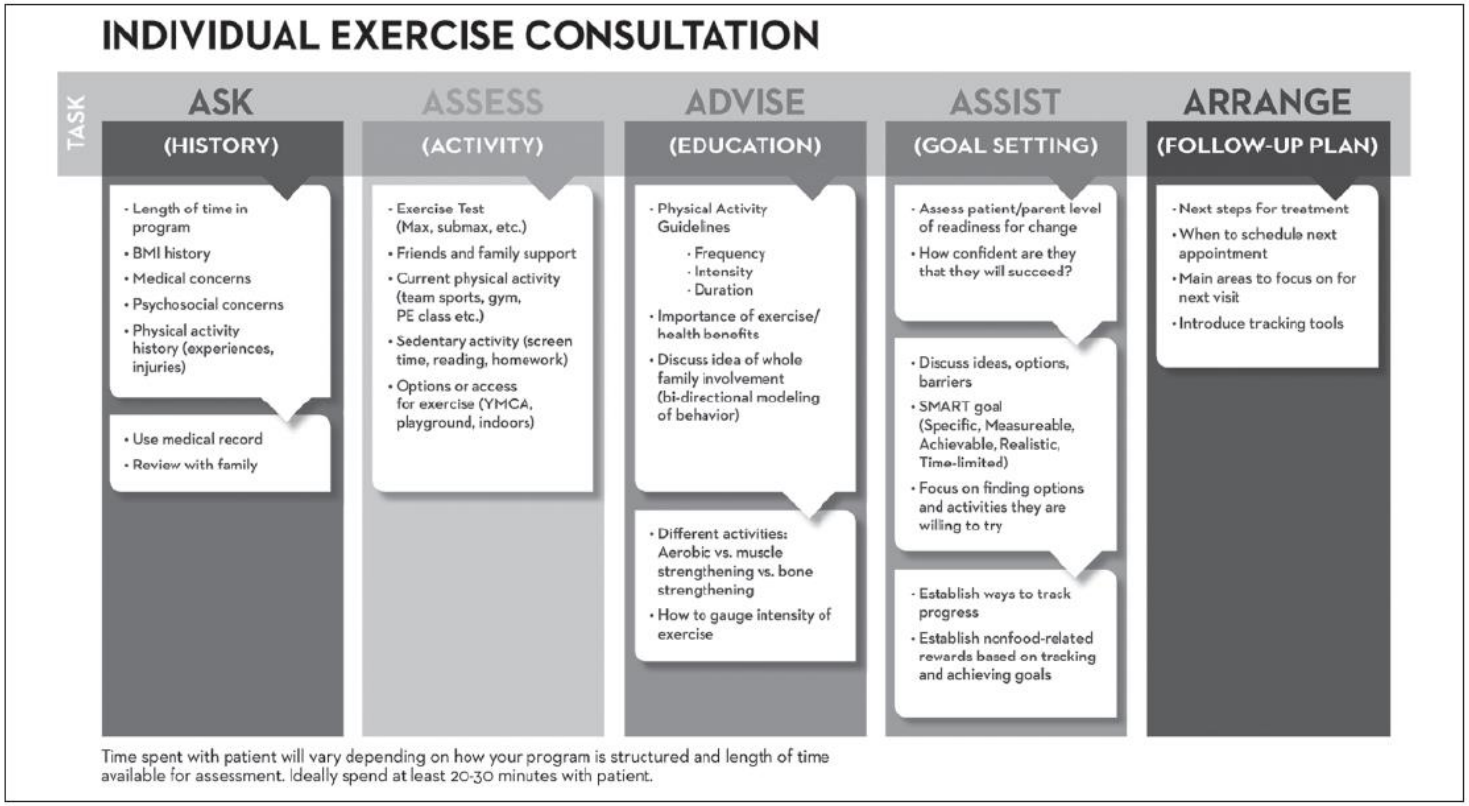
Objective measures are preferable in clinical settings since subjective physical activity assessments are prone to social desirability bias, and because physical activity patterns among youth are typically sporadic and difficult to recall accurately. When selecting the most appropriate measurement tool, clinical programs should consider which physical activity factors (ie, duration, frequency, and intensity) are the primary treatment target, while also factoring in cost limitations.



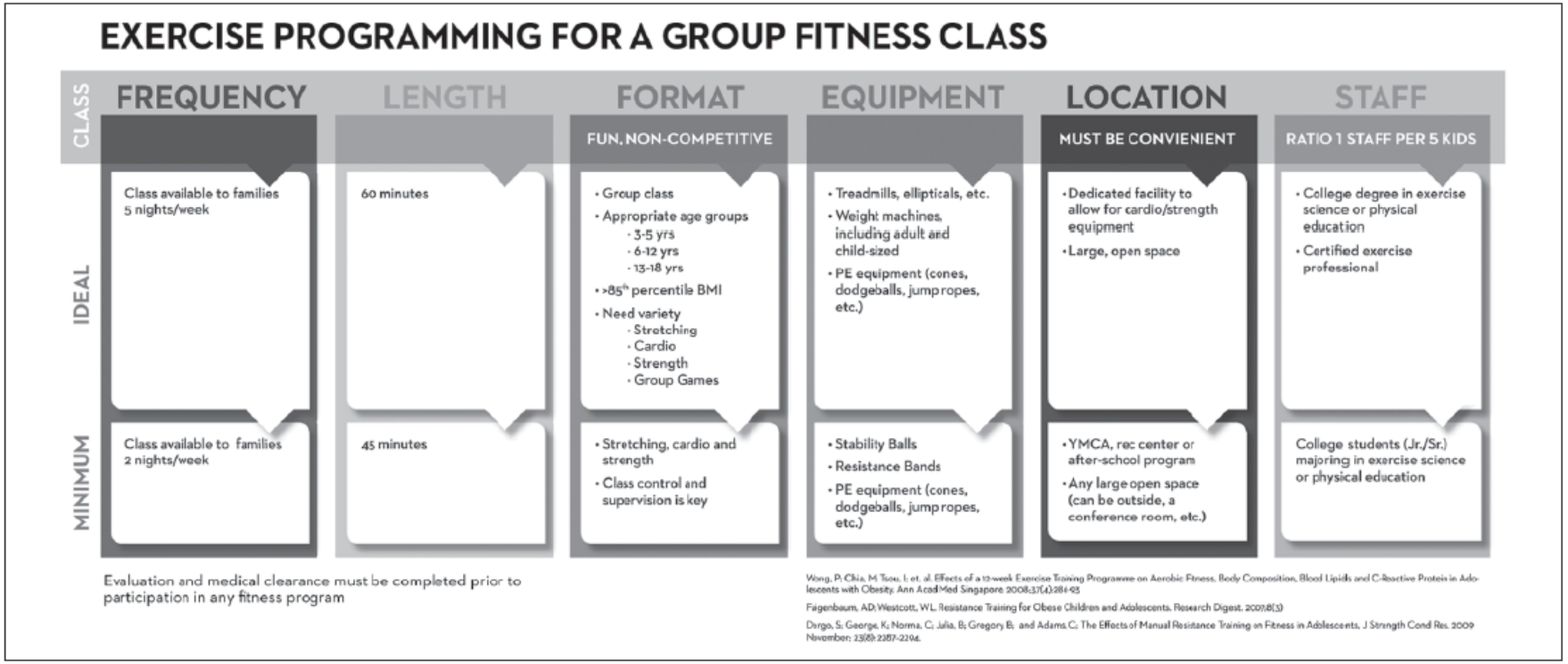
Preliminary research suggests sedentary behavior may also adversely affect youth. Thus, sedentary behavior and physical activity should be assessed together to determine an individual's overall level of energy expenditure. Measures of sedentary behavior include objective devices, such as accelerometers and subjective tools, such as direct interviews and self-report questionnaires.



Individual exercise consultants can be beneficial for patients and families and should be included in a clinical weight management program. Consults are conducted with the patient and accompanying family members. Information previously gathered through exercise testing, body composition analysis, and physical activity and sedentary behavior assessments should be used during these sessions.



Group exercise programming is another important consideration for weight management programs and may be included in a patient's exercise prescription. Exercise classes can offer an effective workout for participants with varying fitness levels, from beginner to the more advanced. Group-based approaches offer opportunities for support from peers, as well as guidance and feedback from a group leader.



The **Children's Hospital Association recommends** registered dietitians (RDs) play an integral role in a comprehensive multidisciplinary weight management programs for overweight and obese youth. This level of intervention is classified as a Stage 3 approach in the current paradigm for treatment of pediatric obesity and has been found to be most effective in improving weight status when clinician contact time is provided at a medium (26 to 75 hours) to high intensity (>75 hours) over a 6-12 month period. The consensus recommendations for nutrition assessment and treatment are provided below:

Consensus Statements for Nutrition Assessment:

Nutrition assessment components vary depending on the clinical setting, patient population, physical findings, availability of laboratory values, and the clinical judgment of the RD. Consensus statements for nutrition assessment in Stage III Pediatric Weight Management programs were

formulated based on the above results from the two surveys and subcommittee discussion, starting with survey items for which >50 percent of respondents indicated use of the concept. FFF RDs agreed unanimously that these values should be utilized. The statements can be used as guides when assessing a child or adolescent with the medical diagnosis of obesity, in conjunction with other available clinical tools. Note: these may be gathered by, or in conjunction with, other providers on the team.

A. Nutrition assessment of anthropometric measures should include the following:
    a. Weight
    b. Height
    c. BMI
    d. BMI percentile/z-score
    e. BMI change
    f. Weight change
    g. Height change
    h. Growth pattern indices/percentile ranks

    Note: The current Centers for Disease Control (CDC) growth charts do not allow for plotting of BMI above the 97th percentile for age. Current practice calculates exact BMI percentile/z-score whenever possible. New growth charts developed at Children's Hospital Colorado define a child's BMI as a percentage of the 95th percentile. These may be used for monitoring a patient's progress over time as well.
B. Nutrition assessment should include assessment of biochemical values.
C. Nutrition assessment is more comprehensive when it includes the physical findings.
D. Nutrition assessment of food and nutrition-related history should include the following
    a. Food and nutrient intake – meal/snack patterns, nutrient composition, current and previous regimens, food intolerance and allergies
    b. Medication/herbal supplements use – medications, OTC medications, and herbal supplements
    c. Knowledge/beliefs/attitudes – feelings/emotions toward nutrition, readiness to change, understanding of nutrition concepts
    d. Behavior – activities and actions taken to achieve goals
    e. Food and supply availability – factors that affect availability of safe, healthy food and supplies
    f. Physical activity and function – evaluate physical, cognitive, sleep habits and sedentary habits
    g. Nutrition-related patient/client-centered measures – perception of nutrition intervention impact
E. Assessment of client history should include the following:
    a. Personal – language, age, education, role in family, ethnicity
    b. Client/Family Medical – disease states, conditions, illnesses
    c. Social – socioeconomic status, housing, medical care support

<u>Consensus Statements for Nutrition Treatment:</u>

Treatment of overweight or obese children and adolescents can play an important role in preventing long-term complications from obesity as well as improving quality of life and self-esteem. The following consensus statements provide a basic framework for treatment. General

counseling approaches are introduced first, followed by more specific lifestyle-based treatments, and then dietary interventions recognized to be effective for pediatric weight management. The overall treatment goal is to provide a positive experience and an achievable plan of care that will help patients successfully achieve a healthier weight and improve health outcomes.

Nutrition treatment should include the following:

- Use family/patient-centered counseling techniques, with the spirit of motivational interviewing.
- If families have not received recommendations in earlier intervention stages or would benefit from behavior changes in the following areas, address these before advancing to other topics. These five areas are easily identified, have an evidence base for effective weight loss and/or maintenance in the family setting and when addressed, may yield improvements in dietary intake and weight within a relatively short period of time.
    - sugar-sweetened beverages (including juice)
    - breakfast consumption
    - meal & snack timing
    - family meals/feeding dynamics
    - eating out
- Interactions and counseling should be culturally sensitive to maximize success.
- When patients present with concerning maladaptive or disordered eating patterns (boredom/emotional eating, binging, etc.), the RD works with the rest of the team, including mental health professionals, to address these issues. Treatment may need to focus on these eating behaviors and related mental health issues before addressing other problems noted in the nutrition assessment.
- Patients and their families need to be followed at a frequency that will facilitate behavior and lifestyle changes to support attainment and maintenance of a healthier weight.
- Specific plans and goals set with families work best if they are focused on food and diet-related behaviors.

<u>Recommendations for comorbid conditions:</u>
Treatment for co-morbid conditions in a Stage 3 program will include the overarching goals of weight stabilization or loss of excess weight, resulting in an improved BMI and BMI percentile/z-score. RDs use medical nutrition therapy to provide specific strategies for dietary and other lifestyle changes according to the specific co-morbidity. In the case of familial hyperlipidemia, healthy lifestyle habits will provide a foundational advantage for additional medical treatment. Thus, RDs provide medical nutrition therapy along with recommendations to support movement toward a healthier weight/BMI.

For additional co-morbid conditions not surveyed in this document, including acanthosis nigricans, insulin resistance, dyslipidemia, hypertension, and fatty liver disease, RDs follow current evidence-based disease-specific treatment protocols for medical nutrition therapy.

The **American Academy of Pediatrics (AAP) recommends** a comprehensive 4-step or staged care approach for weight management that includes the following stages: (1) prevention plus; (2) structured weight management; (3) comprehensive multidisciplinary intervention; and (4) tertiary care intervention.

AAP suggests that providers encourage healthy behaviors while using techniques to motivate patients and families, and interventions should be tailored to the individual child and family. Although more intense treatment stages will generally occur outside the typical office setting, offices can implement less intense intervention strategies. The APP recommends addressing specific patient behavior goals but also encouraging practices to modify office systems to streamline office-based care and to prepare to coordinate with professionals and programs outside the office for more intensive interventions.

Stage 3 - Comprehensive Multidisciplinary Intervention: This stage consists of increased intensity of behavioral change strategies, greater frequency of patient-provider contact, and more involvement of specialists in treatment. Ideally the patient is referred to a multidisciplinary obesity care team to provide specialized treatment. The eating and activity goals build off the first two stages and are the following: (1) planned negative energy balance achieved through structured diet and physical activity (ME); (2) structured behavioral modification program, including food and activity monitoring and development of short-term diet and physical activity goals (CE); (3) involvement of primary caregivers/families for behavioral modification for children <12 years of age (CE); (4) provision of training for all families to improve the home environment (suggest); and (5) frequent office visits. Weekly visits for a minimum of 8 to 12 weeks seem to be most efficacious (CE), and subsequent monthly visits help maintain new behaviors. Group visits may be more cost-effective and have therapeutic benefit (ME).

Stage 4 – Tertiary Care Invention: Components include referral to a pediatric tertiary weight management center and includes treatment such as continued diet and activity cocounseling and consideration of additions such as meal replacement, a very-low-energy diet, medication and surgery. Two medications have been approved by the FDA for use in adolescents, including sibutramine, a serotonin reuptake inhibitor that increases weight loss by decreasing appetite, and orlistat, which causes fat malabsorption through inhibition of enteric lipase. To be effective, these medication must be used in conjunction with diet and exercise. Generally, gastric bypass has been used to treat only severely obese adolescents who have not improved their weight or health with behavioral interventions. Adolescents who undergo this procedure require careful medical, psychological, and emotional evaluation before surgery and prolonged nutritional and psychological support after surgery.

Guideline Ratings

Guideline Issuer and Date	USPSTF 2017	FFF 2016	CHA 2016	AAP 2015
1. Transparency	A	A	B	C
2. Conflict of interest	A	A	NR	NR
3. Development group	A	B	C	B
4. Systematic Review	A	C	C	B
5. Supporting evidence	A	C	B	B

6. Recommendations	A	C	B	B
7. External Review	A	NR	NR	NR
8. Currency and updates	A	B	B	C

See appendix B for full description of the Trustworthy Guideline grading system.

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Appendix A. GRADE criteria for rating a body of evidence on an intervention

Developed by the GRADE Working Group

Grades and interpretations:

High: Further research is very unlikely to change our confidence in the estimate of effect. Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low: Any estimate of effect is very uncertain.

Type of evidence and starting level

Randomized trial–high Observational study–low Any other evidence–very low

Criteria for increasing or decreasing level

Reductions Study quality has serious (–1) or very serious (–2) problems Important inconsistency in evidence (–1) Directness is somewhat (–1) or seriously (–2) uncertain Sparse or imprecise data (–1) Reporting bias highly probable (–1) **Increases** Evidence of association† strong (+1) or very strong (+2) †Strong association defined as significant relative risk (factor of 2) based on consistent evidence from two or more studies with no plausible confounders Very strong association defined as significant relative risk (factor of 5) based on direct evidence with no threats to validity.

Appendix B. Trustworthy Guideline rating scale

The University of Pennsylvania's Center for Evidence-Based Practice Trustworthy Guideline rating scale is based on the Institute of Medicine's "Standards for Developing Trustworthy Clinical Practice Guidelines" (IOM), as well as a review of the AGREE Enterprise and Guidelines International Network domains.

The purpose of this scale is to focus on the weaknesses of a guideline that may reduce the trust a clinical user can have in the guideline, and distinguish weaknesses in documentation (e.g. guide-line does not have a documented updating process) from weaknesses in the guidance itself (e.g. recommendations are outdated). Current quality scales like AGREE emphasize documentation. They are important checklists for developers of new guidelines, but are less useful for grading existing guidelines. These scales also are harder for clinicians and other persons who are not methodology experts to apply, and their length discourages their use outside formal technology assessment reports. This new scale is brief, balanced, and easy and consistent to apply.

We do not attempt to convert the results of this assessment into a numeric score. Instead we present a table listing the guidelines and how they are rated on each standard. This facilitates qualitative understanding by the reader, who can see for what areas the guideline base as a whole is weak or strong as well as which guidelines are weaker or stronger.

1. Transparency

A	Guideline development methods are fully disclosed.
B	Guideline development methods are partially disclosed.
C	Guideline development methods are not disclosed.

The grader must refer to any cited methods supplements or other supporting material when evaluating the guideline. Methods should include:

Who wrote the initial draft
How the committee voted on or otherwise approved recommendations

Evidence review, external review and methods used for updating are not addressed in this standard.

2. Conflict of interest

A	Funding of the guideline project is disclosed, disclosures are made for each individual panelist, and financial or other conflicts do not apply to key authors of the guideline or to more than 1 in 10 panel members).

B	Guideline states that there were no conflicts (or fewer than 1 in 10 panel members), but does not disclose funding source.
C	Lead author, senior author, or guideline panel members (at least 1 in 10) have conflict of interest, or guideline project was funded by industry sponsor with no assurance of independence.
NR	Guideline does not report on potential conflict of interests.

For purposes of this checklist, conflicts of interest include employment by, consulting for, or holding stock in companies doing business in fields affected by the guideline, as well as related financial conflicts. This definition should not be considered exclusive. As much as anything, this is a surrogate marker for thorough reporting, since it may be assumed that guideline projects are funded by the sponsoring organization and many authors think it unnecessary to report a non-conflict.

3. Guideline development group

A	Guideline development group includes 1) methodological experts and clinicians and 2) representatives of multiple specialties.
B	Guideline development group includes one of the above, but not both.
C	Guideline developers all from one specialty or organization, and no methodologists.
NR	Affiliations of guideline developers not reported

The purpose of this standard is to ensure that supporters of competing procedures, or clinicians with no vested interest in utilization of one procedure or another, are involved in development of the guideline. Both AGREE II and IOM call for patient or public involvement: very few guideline panels have done so to date, so this is not necessary for guidelines to be rated A. Involvement of methodologists or HTA specialists in the systematic review is sufficient involvement in the guideline development group for our purposes. In the absence of any description of the guideline group, assume the named authors are the guideline group.

4. Systematic review

A	Guideline includes a systematic review of the evidence or links to a current review.
B	Guideline is based on a review which may or may not meet systematic review criteria.
C	Guideline is not based on a review of the evidence.

In order to qualify as a systematic review, the review must do all of the following:

Describe itself as systematic or report search strategies using multiple databases
Define the scope of the review (including key questions and the applicable population)
Either include quantitative or qualitative synthesis of the data or explain why it is not indicated

Note: this element does not address the quality of the systematic review: simply whether or not it exists. Concerns about quality or bias of the review will be discussed in text, where the analyst will explain whether the weaknesses of the review weaken the validity or reliability of the guideline.

Note: a guideline may be rated B on this domain even if the review on which it is based is not available to us. This potential weakness of the guideline should be discussed in text of the report.

5. Grading the supporting evidence

A	Specific supporting evidence (or lack thereof) for each recommendation is cited and graded
B	Specific supporting evidence (or lack thereof) for each recommendation is cited but the recommendation is not graded.
C	Recommendations are not supported by specific evidence.

To score a B on this domain there should be specific citations to evidence tables or individual references for each relevant recommendation in the guideline, or an indication that no evidence was available. Any standardized grading system is acceptable for purposes of this rating. If a guideline reports that there is no evidence available despite a thorough literature search, it may be scored B on this domain, or even A if evidence for other recommendations is cited and graded.

6. Recommendations

A	Considerations for each recommendation are documented (i.e. benefits and harms of a particular action, and/or strength of the evidence); and recommendations are presented in an actionable form.
B	Either one or the other of the above criteria is met.
C	Neither of the above criteria are met

In order to be actionable, the guideline should specify the specific population to which the guideline applies, the specific intervention in question, and the circumstances under which it should be carried out (or not carried out). The language used in the recommendations should also be consistent with the strength of the recommendation (e.g. directive and active language like “should” or “should not” for strong recommendations, and passive language like “consider” for weak recommendations). A figure or algorithm is considered actionable as long as it is complete enough to incorporate all the applicable patients and interventions. Please see the forthcoming NICE manual (24) for a good discussion of actionability in guidelines.

7. External review

A	Guideline was made available to external groups for review.
B	Guideline was reviewed by members of the sponsoring body only.
C	Guideline was not externally reviewed.
NR	No external review process is described.

8. Updating and currency of guideline

A	Guideline is current and an expiration date or update process is specified.
B	Guideline is current but no expiration date or update process is specified.
C	Guideline is outdated.

A guideline is considered current if it is within the developers' stated validity period, or if no period or expiration data is stated, the guideline was published in the past three years (NOTE: the specific period may be changed at the analyst's discretion, based on whether the technology is mature and whether there is a significant amount of recent evidence). A guideline must address new evidence when it is updated. A guideline which is simply re-endorsed by the panel without searching for new evidence must be considered outdated