ADHD Measure 2: Behavior Therapy

SNAC Submission Form Section 5: Evidence

Attachment 1: AAP Guideline Evidence

## Excerpt from the 2011 AAP ADHD Guideline: Preschool-aged Children

Attention-deficit/hyperactivity disorder (ADHD) is the most common neurobehavioral disorder of childhood and can profoundly affect the academic achievement, well-being, and social interactions of children; the American Academy of Pediatrics (AAP) first published clinical recommendations for diagnosis and evaluation of ADHD in a child in 2000; recommendations for treatment followed in 2001. New information and evidence regarding the diagnosis and treatment of ADHD as well as increased understanding of the disorder and the challenges it raises for clinicians seeking to evaluate, diagnose, and treat ADHD in children inform and support the current guideline, which updates and replaces the previous publications. ADHD occurs in approximately 8% of children and youth, and the number of children with this condition is far greater than can be managed by the mental health system. There is now increased evidence that appropriate diagnosis can be provided for preschool-aged children (4-6 years of age) and for adolescents.

## **Expanded Age Range**

The previous guidelines addressed diagnosis and treatment of ADHD in children 6 through 12 years of age. There is now emerging evidence to expand the age range of the recommendations to include preschool children and adolescents.

Methodology

## **Evidence Review Process for Treatment**

See the 2011 AAP ADHD Guideline (Section 5, Attachment 5) for the full description of the methodology for the review of the evidence

In addition to this systematic review, for treatment, we used the review by the ......EPC, for the Agency for Healthcare Research and Quality (AHRQ). This review addressed a number of key questions for the committee, including the efficacy of medications and behavioral interventions for preschoolers, children, and adolescents. Evidence identified through the systematic evidence review for diagnosis was also used as a secondary data source to supplement the evidence presented in the AHRQ report. Action statements labeled Strong Recommendation or Recommendation were based on high- to moderate-quality scientific evidence and a preponderance of benefit over harm. The Action Statement for treatment of preschool-aged children had an assessed Quality of Evidence of A (Strong Recommendation).

Action Statement 5: Recommendations for treatment of children and youth with ADHD varies depending on their age:

5a. For preschool-aged children (4 through 5 years of age), the primary care clinician should prescribe evidence-based parent- and/or teacher-administered behavior therapy as the first line of treatment (Quality of Evidence: A/Strong Recommendation) and may prescribe treatment with methylphenidate if behavior interventions have not provided adequate improvement and there is moderate to severe continuing disturbance in the child's function. In areas where evidence-based behavioral treatments are not available, the clinician needs to weigh the risks of starting medication at an early age against the harm of delaying diagnosis and treatment (Quality of Evidence: B/Recommendation).

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A for behavior; B for methylphenidate.
Both behavior therapy and methylphenidate have been demonstrated to reduce behaviors associated with ADHD and improve function.
Both therapies increase the cost of care, and behavior therapy requires a higher level of family involvement, whereas methylphenidate has some potential adverse effects.
Given the risks of untreated ADHD, the benefits outweigh the risks.
The committee members included the effects of untreated ADHD when deciding to make this recommendation.
Family preference is essential in determining the treatment plan.
None.
None.
Strong recommendations.

As was identified in the previous guideline, the most common stimulant adverse effects are appetite loss, abdominal pain, headaches, and sleep disturbance. The results of the Multimodal Therapy of ADHD (MTA) study have identified a more persistent effect of stimulants on decreasing growth velocity than have most previous studies, particularly when children were on higher and more consistently administered doses. The effects diminished by the third year of treatment, but no compensatory rebound effects were found. vi However, diminished growth was in the range of 1 to 2 cm. An uncommon additional significant adverse effect of stimulants is the occurrence of hallucinations and other psychotic symptoms. vii Although concerns have been raised about the rare occurrence of sudden cardiac death among children using stimulant medications, viii sudden death in children on stimulant medication is extremely rare, and evidence is conflicting as to whether stimulant medications increase the risk of sudden death. ix,x,xi It is important to expand the history to include specific cardiac symptoms. Wolf-Parkinson-White syndrome, sudden death in the family, hypertrophic cardiomyopathy, and long QT syndrome. Preschool-aged children may experience increased mood lability and dysphoria. xii For the nonstimulant atomoxetine, the adverse effects include initial somnolence and gastrointestinal tract symptoms, particularly if dosage is increased too rapidly; decrease in appetite; less commonly, an increase in suicidal thoughts; and rarely, hepatitis. For the nonstimulant alpha-2-adrenergic agonists extended-release guanfacine and clonidine, adverse effects include somnolence and dry mouth.

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# Special Circumstances in the diagnosis of Preschool-Aged Children

There is evidence that the diagnostic criteria for ADHD can be applied to preschool-aged children; however, the subtypes detailed in the DSM-IV may not be valid for this population. XIII, XIV, XV, XVI, XVIII, XVIIII, XVIII

When there are concerns about the availability or quality of nonparent observations of a child's behavior, physicians may recommend that parents complete a parent training program before confirming an ADHD diagnosis for preschool-aged children and consider placement in a qualified preschool program if they have not done so already. Information can be obtained from parents and teachers through the use of validated DSM-IV-based ADHD rating scales. The parent training program must include helping parents develop age-appropriate developmental expectations and specific management skills for problem behaviors. The clinician may obtain reports from the parenting class instructor about the parents' ability to manage their children, and if the children are in programs where they are directly observed, instructors can report information about the core symptoms and function of the child directly. Qualified preschool programs include programs such as Head Start or other public pre-K programs. Preschool children displaying significant emotional or behavioral concerns may also qualify for Early Childhood Special Education services through their local school districts, and the evaluators for these programs and/or Early Childhood Special Education teachers may be excellent reporters of core symptoms.

## Special Considerations in the Treatment of Pre-school Age Children

A number of special circumstances support the recommendation to initiate ADHD treatment of preschool-aged children (age 4-6) with behavioral therapy alone first. $^{xii}$  These include:

- The multisite study of methylphenidate<sup>xii</sup> was limited to preschool age children who had moderate to severe dysfunction;
- The study has demonstrated that many children (age 4-5) experience improvements in symptoms with behavior therapy alone and the overall evidence for behavior therapy in preschoolers is strong.
- These programs typically run in the form of group parent training programs, and although not always
  compensated by health insurance, are at a lower cost. The Process Algorithm contains criteria for the
  clinician to use in assessing the quality of the behavioral therapy. In addition, programs such as Head
  Start and Children and Adults with Attention Deficit Hyperactivity Disorder (CHADD) may provide some
  behavioral supports.

Many young children with ADHD may still require medication to achieve maximum improvement, and medication is not contraindicated for children 4 through 6 years of age. However, only 1 study has carefully assessed medication use in preschool-aged children. Other considerations in the recommendation about treating children 4-6 years of age with stimulant medications include:

The study was limited to preschool-aged children who had moderate to severe dysfunction;

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- Research has demonstrated that many young children (4-5 years of age) experience improvements in symptoms with behavior therapy alone;
- Concerns about whether the effects of medication on growth and other adverse effects may be heightened for preschool-aged children; and
- There is limited information and experience about the effects of stimulant medication between the ages of 4 and 6 years.

Here, the criteria for enrollment (and, therefore, medication use) included measures of severity that distinguished treated children from the larger group of preschool-aged children with ADHD. Thus, prior to initiating medications, the physician should assess the severity of the child's ADHD. Given current data, only those preschool-aged children with ADHD who have moderate to severe dysfunction should be considered for medication. Criteria for this level of severity, on the basis of the multisite study, if are: (1) symptoms that have persisted for at least 9 months; (2) dysfunction that is manifested in both home and other settings, such as preschool or child care; and (3) dysfunction that has not responded adequately to behavior therapy. The decision to consider initiating medication at this age depends in part on the clinician's assessment of the estimated developmental impairment, safety risks, or consequences for school or social participation that could ensue if medications are not initiated. It is often helpful to obtain consultation from a mental health specialist with specific experience with preschool-aged children if possible.

Dextroamphetamine is the only medication approved by the FDA for use in children 4 through 6 years of age, but that approval is based on less stringent criteria in force when the medication was approved rather than on empirical evidence of its safety and efficacy in this age group. Most of the evidence about the safety and efficacy of treating preschool-aged children with stimulant medications has been limited to methylphenidate. Methylphenidate evidence consists of 1 multisite study of 165 children and 10 other single—site, smaller studies ranging from 11 to 59 children, with a total of 269 children; 7 of the 10 single-site studies demonstrated significant efficacy. It must be noted that although there is moderate evidence that methylphenidate is safe and efficacious in preschool-aged children, its use in preschool-aged children remains an "off label" use of methylphenidate, and although the use of dextroamphetamine is on-label, the insufficient evidence for its safety and efficacy in this age groups does not make it possible to be recommended at this time.

If children do not experience adequate symptom improvement with behavior therapy, medication can be prescribed, as described previously. Evidence suggests that the rate of metabolizing stimulant medication is slower in children 4 through 6 years of age, so they should be given a lower dose to start, and the dose can be increased in smaller increments. Maximum doses have not been adequately studied. xii

## **Behavior Therapy**

Behavior therapy represents a broad set of specific interventions that have a common goal of modifying the physical and social environment to alter or change behavior. Behavior therapy usually is implemented by training parents in specific techniques that improve their abilities to modify and shape their child's behavior and to improve the child's ability to regulate his or her own behavior. The training involves techniques to more effectively provide rewards when their child demonstrates the desired behavior (eg, positive reinforcement), learn what behaviors will extinguish by using planned ignoring as an active strategy (or using praising and ignoring in combination), or provide appropriate consequences or punishments when their child fails to meet the goals (eg, punishment). Consistently applying rewards and consequences for achievable tasks and gradually increasing the demands for each task as they are

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mastered shapes behavior. Although behavior therapy shares a set of principles, individual programs introduce different techniques and strategies to achieve the same ends.

Table 1. Evidence-Based Psychosocial Treatments for ADHD

Intervention Type	Description	Typical Outcome(s)	Median Effect Size <sup>1</sup>
Behavioral Parent Training (BPT)	Behavior modification principles provided to parents for implementation in home settings	<ul> <li>Improved compliance with parental commands</li> <li>Improved parental understanding of behavioral principles</li> <li>High levels of parental satisfaction with treatment</li> </ul>	0.55
Behavioral Classroom Management	Behavior modification principles provided to teachers for implementation in classroom settings	<ul> <li>Improved attention to instruction</li> <li>Improved compliance with classroom rules</li> <li>Decreased disruptive behavior</li> <li>Improved work productivity</li> </ul>	0.61
Behavioral Peer Interventions (BPI) <sup>2</sup>	Interventions focused on peer interactions/relationships. These are often group-based interventions provided weekly and include clinic-based social skills training employed either alone or concurrently with behavioral parent training and/or medication.	Office-based interventions have produced minimal effects. Interventions have been of questionable social validity. Some studies of BPI combined with clinic-based BPT report positive effects on parent ratings of ADHD symptoms. No differences on social functioning or parent ratings of social behavior have been revealed.	

<sup>[1]</sup> Effect Size = (Treatment M – Control M)/Control SD. <sup>2</sup>The effect size for behavioral peer interventions is not reported, because the effect sizes for these studies represent outcomes associated with combined interventions. A lower effect size means they have less of an effect. The effect sizes found are considered moderate. Adapted from Pelham WE, Fabiano GA. Evidence-based psychosocial treatment for attention-deficit/hyperactivity disorder. *J Clin Child Adolesc Psychol*. 2008;37(1):184-214.

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Evidence for the effectiveness of behavior therapy in children with ADHD is derived from a variety of studies xxi,xxii,xxiii and the Agency for Healthcare Research and Quality review. The diversity of interventions and outcome measures makes meta-analysis of the effects of behavior therapy alone or in association with medications challenging. The long-term positive effects of behavior therapy have yet to be determined. Ongoing adherence to a behavior program may be important, and therefore, implementing a Chronic Care Model for Child Health may contribute to the long-term effects. xxiv

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iv Attention Deficit Hyperactivity Disorder: Effectiveness of Treatment in At-risk Preschoolers; Long-term Effectiveness in All Ages; and Variability in Prevalence, Diagnosis, and Treatment. *In Press* 

<sup>&</sup>lt;sup>v</sup> American Academy of Pediatrics, Steering Committee on Quality Improvement. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874-877

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