

Guidelines for Prescribing Psychotropic Medication to Children Under 6 Years

Diagnosis	1 <sup>st</sup> Line Treatment	2 <sup>nd</sup> Line Treatment	3 <sup>rd</sup> Line Treatment
<p>ADHD</p> <p>Diagnostic Assessment /Screening Tool</p> <ul style="list-style-type: none"> <li>▪ ADHD Rating Scale – IV Preschool or Connors Early Childhood - EC</li> </ul>	<p>Psychotherapeutic Trial</p> <ul style="list-style-type: none"> <li>▪ Parent Behavior Training (PBT) interventions (Charach 2013)</li> </ul>	<p>Methylphenidate/Dexamethylphenidate</p> <ul style="list-style-type: none"> <li>▪ Initial liquid dose 1-5 mg (Gleason 2007)</li> <li>▪ Tapering is not recommended for stimulants</li> </ul> <p><u>Side Effects</u></p> <ul style="list-style-type: none"> <li>▪ Review family/child history of heart condition*</li> <li>▪ Loss of appetite - severely underweight (3<sup>rd</sup> percentile)**</li> <li>▪ Stomach and/or head ache</li> <li>▪ Irritability/moodiness (Charach 2013)</li> <li>▪ Increased blood pressure and pulse</li> <li>▪ Rebound insomnia/sedation</li> </ul>	<p>Amphetamine Formulations</p> <ul style="list-style-type: none"> <li>▪ Initial liquid dose 1-5 mg (Gleason 2007)</li> <li>▪ Tapering is not recommended for stimulants</li> </ul> <p><u>Side Effects</u></p> <ul style="list-style-type: none"> <li>▪ As effective as methylphenidate in older children but no randomized controlled trials in children under 5.</li> <li>▪ Review family/child history of heart condition*</li> <li>▪ Loss of appetite - severely underweight (3<sup>rd</sup> percentile)**</li> <li>▪ Stomach and/or head ache</li> <li>▪ Irritability/moodiness (Charach 2013)</li> <li>▪ Increased blood pressure and pulse</li> <li>▪ Rebound insomnia/sedation</li> </ul>
<b>4<sup>th</sup> Line Treatment</b>			
<p>Alpha-Agonists</p> <ul style="list-style-type: none"> <li>▪ Careful consideration of age and body weight, initial low liquid doses                             <ul style="list-style-type: none"> <li>◦ Clonidine initial dosage of 0.025-0.05mg up to 0.1 mg/day at bedtime (Ming 2008) (Ingrassia 2005) maximum 0.3 mg with divided doses (Banaschewski 2004, Hirota 2014). A higher dosing range may be needed if there is significant comorbid diagnoses (Gleason 2007).</li> <li>◦ Guanfacine initial dosage of 0.5 mg/day with a 0.5 mg increment every third day to a therapeutic dosage of between 1 – 3 mg/day (Hunt 1995) (Scahill 2006)</li> </ul> </li> <li>▪ If planning discontinuation, these medications must be tapered</li> </ul> <p><u>Side Effects</u></p> <ul style="list-style-type: none"> <li>▪ Sedation</li> <li>▪ Irritability</li> <li>▪ Headache</li> <li>▪ Bradycardia</li> <li>▪ Hypotention – monitor blood pressure and heart rate***</li> </ul>		<p>Atomoxetine</p> <ul style="list-style-type: none"> <li>▪ Initial liquid dose of 0.5 mg/kg/day with a maximum of 1.6 mg/kg/day (Kratochvil 2009)</li> </ul> <p><u>Side Effects</u></p> <ul style="list-style-type: none"> <li>▪ Mood Liability</li> <li>▪ Decreased appetite</li> <li>▪ Sleepiness</li> <li>▪ Abdominal Pain</li> </ul>	

\* If there is a family history of structural heart disease or an arrhythmia, or if the patient has a heart condition, the patient should have a baseline ECG. Contact the child’s PCP to discuss safety issues. For more complicated cardiac pathology, an echocardiogram or a cardiology consultation may be indicated.

\*\* If the patient loses weight such that his/her weight drops 2 percentile lines on a standard growth curve or if his/her weight falls below the 3<sup>rd</sup> percentile, the medication should be discontinued. The child may need a referral for a growth delay evaluation.

\*\*\* A baseline ECG is not indicated unless the patient has a pre-existing arrhythmia or cardiac disease.

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<p>Anxiety</p> <p>Diagnostic Assessment /Screening Tool</p> <ul style="list-style-type: none"> <li>Spence Preschool Anxiety Scale: Parent Report - free tool to help assess children ages 3-6 with anxiety.</li> </ul> <p>Anxiety</p> <p><a href="http://www.scasweb site.com/docs/scas-preschool-scale.pdf">http://www.scasweb site.com/docs/scas-preschool-scale.pdf</a></p> <ul style="list-style-type: none"> <li>Ages and Stages Questionnaire: Social Emotional (ASQ-SE)</li> </ul>	<p>Psychotherapeutic Trial</p> <ul style="list-style-type: none"> <li>Behavioral therapy or preschool CBT (Geller and March 2012) for a minimum of 12 weeks</li> <li>Parenting intervention for anxiety without mood disorder (Luby 2013)</li> </ul>	<p>Fluoxetine (last resort intervention)</p> <ul style="list-style-type: none"> <li>Initial low dose 2.5mg – 5mg to improve tolerability of SSRI (Fanton and Gleason 2009)</li> <li>Planned discontinuation after 6-9 months</li> </ul> <p><u>Side Effects</u></p> <ul style="list-style-type: none"> <li>Headache</li> <li>Gastric distress</li> <li>Insomnia or increased motor activity</li> <li>Behavioral activation /disinhibition may be more frequent in younger children and children with comorbid ADHD or CNS disorders (Sakolsky and Birmaher 2008)</li> <li>Black box warning: SSRIs potentiate the risk for suicidal thinking</li> <li>With use of Fluoxetine, please review cytochrome P-450 interactions with any other medications the child is taking i.e. asthma medications, antibiotics, antiepileptic medications etc.</li> </ul>	<p>Sertraline (last resort intervention)</p> <ul style="list-style-type: none"> <li>Initial low dose of 5-10mg/day with range up to 25mg (Fanton and Gleason 2009)</li> <li>Planned discontinuation after 6-9 months</li> </ul> <p><u>Side Effects</u></p> <ul style="list-style-type: none"> <li>Headache</li> <li>Gastric distress</li> <li>Insomnia or increased motor activity</li> <li>Behavioral activation /disinhibition may be more frequent in younger children and children with comorbid ADHD or central nervous system disorders (Sakolsky and Birmaher 2008)</li> <li>Black box warning: SSRIs potentiate the risk for suicidal thinking</li> <li>With use of Sertraline, please review cytochrome P-450 interactions with any other medications the child is taking i.e. asthma medications, antibiotics, antiepileptic medications etc.</li> </ul>

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<p>Autism Spectrum Disorder</p> <p>Diagnostic Assessment /Screening Tool</p> <ul style="list-style-type: none"> <li>▪ Child Autism Rating Scale</li> </ul>	<p>Psychotherapeutic Trial</p> <ul style="list-style-type: none"> <li>▪ Parent psychoeducation</li> <li>▪ Early intervention to address (Gleason 2007):                             <ul style="list-style-type: none"> <li>◦ Language</li> <li>◦ Social development</li> <li>◦ Adaptive functioning</li> <li>◦ Reduction in repetitive behaviors</li> <li>◦ Aggression</li> <li>◦ Tantrums</li> <li>◦ Self injury</li> <li>◦ Hyperactivity</li> <li>◦ Anxiety and Mood</li> </ul> </li> </ul> <p>Dysregulation (if significant comorbid problems, please refer to those disorders in this guideline)‡</p> <ul style="list-style-type: none"> <li>◦ Sensory sensitivity ‡</li> </ul> <ul style="list-style-type: none"> <li>▪ Behavioral Therapy (Kaplan and McCracken 2012) Applied Behavioral Analysis (ABA) gold standard</li> </ul> <p>‡ Not from Gleason 2007</p>	<p>Irritability and Aggression</p> <p>Risperidone</p> <ul style="list-style-type: none"> <li>▪ Initial liquid dose 0.1 – 1.5mg/day with a maximum dosage of 3mg/day</li> </ul> <p><u>Side Effects</u></p> <ul style="list-style-type: none"> <li>▪ Metabolic Syndrome (weight gain)</li> <li>▪ Elevation of serum prolactin</li> <li>▪ FDA indication for irritability and aggression in children aged 5 to 16 years with autistic disorder and symptoms of aggression, self-injury, temper tantrums and mood swings (Kaplan and McCracken 2012)                             <ul style="list-style-type: none"> <li>▪ Close monitoring of patients is essential</li> </ul> </li> </ul>	<p>Irritability and Aggression</p> <p>Aripiprazole*</p> <ul style="list-style-type: none"> <li>▪ Initial liquid dose of 0.2 - 3 mg with a maximum of 7.5mg (Leucht 2014) Using dose equivalents due to insufficient research in the preschool population.</li> </ul> <p>Guanfacine initial dosage of 0.5 mg/day with a 0.5 mg increment every third day to a therapeutic dosage of between 1 – 3 mg/day (Hunt 1995) (Kaplan and McCracken 2012)(Scahill 2006) or Clonidine initial dosage of 0.025-0.05mg up to 0.1 mg/day at bedtime (Ming 2008) (Ingrassia 2005)</p> <p><u>Side Effects</u> (Kaplan and McCracken 2012)</p> <ul style="list-style-type: none"> <li>▪ FDA indication for 6-17 years</li> <li>▪ Good results in school aged population</li> <li>▪ Sedation</li> <li>▪ Weight gain</li> <li>▪ Extrapyramidal symptoms</li> <li>▪ Presyncope with unsteady gait (Owen 2009)</li> </ul>
		<p>Hyperactivity</p> <p>Methylphenidate</p> <ul style="list-style-type: none"> <li>▪ Initial liquid dose 1-5mg</li> </ul> <p><u>Side Effects</u></p> <ul style="list-style-type: none"> <li>▪ The rate of intolerability in children with ASD is the double (18%) that of typically developing children with ADHD (Kaplan &amp; McCracken 2012)</li> <li>▪ Family/child history of heart condition</li> <li>▪ Loss of appetite - severely underweight (3<sup>rd</sup> percentile)</li> <li>▪ Stomach and/or head aches</li> <li>▪ Irritability</li> <li>▪ Increased blood pressure and pulse</li> <li>▪ Agitation</li> <li>▪ Mood changes</li> <li>▪ Abnormal movements (Kaplan &amp; McCracken 2012)</li> <li>▪ Rebound insomnia/sedation</li> </ul>	<p>Hyperactivity</p> <p>Alpha-Agonists</p> <p>Guanfacine initial dosage of 0.5 mg/day with a 0.5 mg increment every third day to a therapeutic dosage of between 1 – 3 mg/day (Hunt 1995) (Kaplan and McCracken 2012) (Scahill 2006) or Clonidine initial dosage of 0.025-0.05mg up to 0.1 mg/day at bedtime (Ming 2008) (Ingrassia 2005). A higher dosing range may be needed if there is significant comorbid diagnoses.</p> <ul style="list-style-type: none"> <li>▪ If discontinuation is planned, these medications must be tapered</li> </ul> <p><u>Side Effects</u></p> <ul style="list-style-type: none"> <li>▪ Sedation</li> <li>▪ Irritability</li> <li>▪ Bradycardia</li> <li>▪ Hypotension (Scahill et al. 2001) – monitor blood pressure and heart rate</li> </ul>

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Autism Spectrum Disorder			<b>4<sup>th</sup> Line Treatment</b>
			Hyperactivity Atomoxetine <ul style="list-style-type: none"> <li>▪ Initial liquid dose of 0.5 mg/kg/day with a maximum of 1.6 mg/kg/day (Kratochvil 2009)</li> </ul> <u>Side Effects</u> <ul style="list-style-type: none"> <li>▪ Mood Liability</li> <li>▪ Decreased appetite</li> <li>▪ Sleepiness</li> <li>▪ Abdominal Pain</li> </ul>
<b>Diagnosis</b>	<b>1st Line Treatment</b>	<b>2<sup>nd</sup> Line Treatment</b>	<b>3<sup>rd</sup> Line Treatment</b>
Autism Spectrum Disorder		Repetitive Behaviors	Repetitive Behaviors
		Fluoxetine (last resort intervention for severe symptoms) <ul style="list-style-type: none"> <li>▪ Initial liquid dose of 2.5 mg/day; week 2 and 3 titrated per subject's weight, symptoms and side effects with a maximum of 0.8 mg/kg/day (Hollander 2005)</li> <li>▪ Planned discontinuation after 6-12 months</li> <li>▪ Not tested on children younger than 5 years</li> </ul> <u>Side Effects</u> <ul style="list-style-type: none"> <li>▪ Headache</li> <li>▪ Gastric distress</li> <li>▪ Insomnia/ increased motor activity</li> <li>▪ Behavioral activation/disinhibition is a more frequent side effect in younger children and children with comorbid ADHD or central nervous system disorders (Sakolsky and Birmaher 2008)</li> <li>▪ Black box warning for all SSRIs potentiate the risk for suicidal thinking</li> </ul>	Fluvoxamine and Escitalopram have evidence supporting use in children 6 years and above but there is no data supporting use in children under 6 (West 2009)

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<p>Bipolar</p> <p>Diagnostic Assessment /Screening Tool</p> <ul style="list-style-type: none"> <li>▪ Young Mania Rating Scales</li> </ul> <p>Note: address mania first, higher incidence of rapid cycling and mixed mania (Peruzzolo et al. 2013)</p>	<p>Psychotherapeutic Trial</p> <ul style="list-style-type: none"> <li>▪ Parent Child Interaction Therapy (PCIT) (Luby 2013)</li> </ul>	<p>Risperidone</p> <ul style="list-style-type: none"> <li>▪ Initial liquid dose 0.1 – 1.5mg/day (Kaplan &amp; McCracken 2012)</li> </ul> <p><u>Side Effects</u></p> <ul style="list-style-type: none"> <li>▪ Metabolic Syndrome</li> <li>▪ Extrapyramidal side effects</li> <li>▪ Elevation of serum prolactin</li> <li>▪ Akathisia</li> </ul>	<p>Aripiprazole (Oh et al 2013)</p> <ul style="list-style-type: none"> <li>▪ Initial liquid dose of 0.2 - 3 mg with a maximum of 7.5mg (Leucht 2014) Using dose equivalents due to insufficient research in the preschool population.</li> </ul> <p><u>Side Effects</u></p> <ul style="list-style-type: none"> <li>▪ Good results in school aged population but no preschool data</li> <li>▪ Sedation</li> <li>▪ Weight gain/Metabolic Syndrome</li> <li>▪ Akathisia</li> <li>▪ Extrapyramidal symptoms</li> <li>▪ Good treatment effects and comparatively mild side-effects to other atypical antipsychotics (Oh et al 2013)</li> </ul> <p>Quetiapine</p> <ul style="list-style-type: none"> <li>▪ Starting dose 2.5 mg /kg /day for a week; increase by 2.5 mg /kg /day for week 2; increase by 3.75 mg /kg /day for week 3; increase by 5.0 mg /kg /day for week 4 – not to exceed a maximum dose of 10 mg /kg /day (Joshi et al 2012)</li> </ul> <p><u>Side Effects</u></p> <ul style="list-style-type: none"> <li>▪ Sedation</li> <li>▪ Metabolic Syndrome/ significant weight gain</li> <li>▪ No extrapyramidal side effects</li> <li>▪ No elevation of serum prolactin</li> </ul>

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<p>Depression</p> <p>Diagnostic Assessment /Screening Tool</p> <ul style="list-style-type: none"> <li>Preschool Feelings Checklist (Luby et al., 2002)</li> </ul>	<p>Psychotherapeutic Trial</p> <ul style="list-style-type: none"> <li>Psychotherapeutic Treatment modalities that address the parent-child relationship such as Parent Child Interaction Therapy-Emotion Development (PCIT-ED)(Lenze et al 2011)</li> </ul>	<p>Fluoxetine (last resort intervention) (Hetrick et al 2012)</p> <ul style="list-style-type: none"> <li>Suggested initial liquid dose 0.5-2mg/day to minimize side effects.</li> <li>5-8mg/day effective treatment dose for this age group (Gleason 2007)</li> <li>Planned discontinuation after 9 months at therapeutic dose (Gleason 2007)</li> </ul> <p><u>Side Effects</u></p> <ul style="list-style-type: none"> <li>Headache</li> <li>Gastric distress</li> <li>Insomnia or increased motor activity</li> <li>Behavioral activation /disinhibition is a more frequent side effect in younger children and children with comorbid ADHD or central nervous system disorders. (Sakolsky and Birmaher 2008)</li> <li>Black box warning: SSRIs potentiate the risk for suicidal thinking</li> <li>With use of fluoxetine, please review cytochrome P-450 interactions with any other medications the child is taking i.e. asthma medications, antibiotics, antiepileptic medications etc.</li> </ul>	<ul style="list-style-type: none"> <li>Clinical experience suggests other SSRIs such as Citalapram and Escitalapram may be easier for preschool children to tolerate. However, with Citalapram prolonged QT intervals at dosages greater than 40mg need to be considered.</li> </ul>
<p>Disruptive Behavior Disorder (DBD) and Aggression</p> <p>Diagnostic Assessment /Screening Tool</p> <p><i>Note: Treat the co-morbid disorders contributing to disruptive behavior first</i></p> <ul style="list-style-type: none"> <li>Eyberg Child Behavior Inventory (ECBI)</li> </ul>	<p>Psychotherapeutic Trial</p> <ul style="list-style-type: none"> <li>Preschool CBT</li> <li>Parent Child Interaction Therapy (PCIT), Incredible Years Program, Collaborative Problem Solving etc. (Luby 2006)</li> <li>Infant/Toddler Parent Programs i.e. Child Parent Interactive Therapy</li> <li>Classroom-Based Interventions Token Reward Systems</li> </ul>	<p>Disruptive/Aggressive Behavior plus any other major mental illness - see that category</p> <p><u>Aggression</u></p> <ul style="list-style-type: none"> <li>Anti psychotics are often used to augment psychotherapy. For <u>severe</u> aggression in preschool age children, an atypical antipsychotic can be prescribed (Lohr and Honaker 2013)</li> </ul> <p><u>Side Effects</u></p> <ul style="list-style-type: none"> <li>Metabolic Syndrome</li> <li>Extrapyramidal side effects</li> <li>Elevation of serum prolactin</li> </ul>	

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<p>Obsessive Compulsive Disorder (OCD)</p> <p>Diagnostic Assessment /Screening Tool</p> <ul style="list-style-type: none"> <li>Spence Preschool Anxiety Scale: Parent Report - free tool to help assess children ages 3-6 with anxiety.</li> </ul> <p><a href="http://www.scasweb site.com/docs/scas-preschool-scale.pdf">http://www.scasweb site.com/docs/scas-preschool-scale.pdf</a></p> <p>(Whiteside et al 2012)</p>	<p>Psychotherapeutic Trial</p> <ul style="list-style-type: none"> <li>CBT using exposure and response prevention techniques and involving parents is recommended (Whiteside et al 2012)</li> </ul>	<p>Fluoxetine and Sertraline (last resort interventions)</p> <ul style="list-style-type: none"> <li>Insufficient evidence to recommend one medication over the other</li> <li>Fluoxetine - initial low dose 2.5mg – 5mg to improve tolerability of SSRI (Fanton and Gleason 2009)</li> <li>Sertraline – initial low dose of 5-10mg/day with range up to 25mg (Fanton and Gleason 2009)</li> <li>Recommended discontinuation after 6-8 months (Coskun and Zoroglu 2009)</li> </ul> <p><u>Side Effects</u></p> <ul style="list-style-type: none"> <li>Has been approved by the Food and Drug Administration (FDA) for the treatment of OCD in children age 7 and up (Rockhill 2010)</li> <li>Behavioral activation /disinhibition is a more frequent side effect in younger children and children with comorbid ADHD or central nervous system disorders. (Sakolsky and Birmaher 2008) A cautious trial of fluoxetine may be an effective treatment for <u>severe</u> OCD in preschool age children. Side effects, particularly behavioral activation/disinhibition, are concerning among the 0-5 population. (Coskun and Zoroglu 2009)</li> <li>Decreased appetite and weight loss</li> <li>Sleep disturbance</li> <li>Headache</li> <li>Abdominal pain</li> <li>With use of Fluoxetine and Sertraline, please review cytochrome P-450 interactions with any other medications the child is taking i.e. asthma medications, antibiotics, antiepileptic medications etc.</li> <li>Given the sensitivity to side effects in the young child population, tapering is recommended</li> </ul>	

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PTSD	Psychotherapeutic Trial <ul style="list-style-type: none"> <li>▪ Child-parent psychotherapy (CPP) for a 6 month trial (Gleason et al., 2007) or preschool CBT for minimum of 12 weeks (Cohen 2003)</li> </ul>	Psychopharmacological interventions are not recommended for children under 6 years based on a lack of research evidence. Talk to a DCFS Psychopharmacology program consultant if symptoms are severe and therapeutic interventions are ineffective.	
Sleep Disturbance  Diagnostic Assessment /Screening Tool  <ul style="list-style-type: none"> <li>▪ Sleep Log</li> </ul>	Parent Education <ul style="list-style-type: none"> <li>▪ Home environment evaluation</li> <li>▪ Sleep hygiene</li> <li>▪ Restless leg syndrome</li> <li>▪ Sleep Apnea</li> <li>▪ Sleep problem associated with other mental health diagnosis</li> <li>▪ Behavior Intervention (2-4 weeks)</li> </ul>	Melatonin <ul style="list-style-type: none"> <li>▪ Impacting well-being and daytime functioning of child and/or caregiver</li> <li>▪ Provide 0.25 - 3mg for preschool age children; administer 5-7 hours before bedtime (Gleason 2007)</li> <li>▪ To treat initial insomnia due to sleep phase delay, a small dose of melatonin (0.25 – 1.0 mg) given 5-7 hours before bedtime to maximize the chronobiotic effect. For use as a soporific, higher doses (3 – 9 mg) given at bedtime may be effective.</li> <li>▪ Over-the-counter</li> <li>▪ Short term use, 1 month maximum before reassessment</li> </ul>	Alpha-agonist (Clonidine) <ul style="list-style-type: none"> <li>▪ Clonidine initial dosage of 0.025-0.05mg up to 0.1 mg/day at bedtime (Ming 2008) (Ingrassia 2005)</li> <li>▪ Short term use, 1 month maximum before reassessment</li> </ul> <u>Side Effects</u> (Pelayo and Yuen 2012) <ul style="list-style-type: none"> <li>▪ Respiratory depression</li> <li>▪ Hypotension</li> <li>▪ Bradycardia</li> <li>▪ Irritability</li> <li>▪ Anticholinergic effects (e.g. dry mouth)</li> <li>▪ REM suppression</li> <li>▪ Parent education about safe administration and monitoring</li> </ul>