### Guidelines for Prescribing Psychotropic Medication to Children Under 6 Years

#### Diagnosis

| ADHD |

#### 1st Line Treatment

- **Psychotherapeutic Trial**
- **Parent Behavior Training (PBT) interventions (Charach 2013)**

#### 2nd Line Treatment

- **Methylphenidate/Dexmethylphenidate**
  - Initial liquid dose 1-5 mg (Gleason 2007)
  - Tapering is not recommended for stimulants

#### Side Effects

- Review family/child history of heart condition* 
- Loss of appetite - severely underweight (3rd percentile)** 
- Stomach and/or head ache 
- Irritability/moodiness (Charach 2013) 
- Increased blood pressure and pulse 
- Rebound insomnia/sedation 

#### 3rd Line Treatment

- **Amphetamine Formulations**
  - Initial liquid dose 1-5 mg (Gleason 2007)
  - Tapering is not recommended for stimulants

#### Side Effects

- As effective as methylphenidate in older children but no randomized controlled trials in children under 5.
- Review family/child history of heart condition* 
- Loss of appetite - severely underweight (3rd percentile)** 
- Stomach and/or head ache 
- Irritability/moodiness (Charach 2013) 
- Increased blood pressure and pulse 
- Rebound insomnia/sedation

#### 4th Line Treatment

- **Alpha-Agonists**
  - Careful consideration of age and body weight, initial low liquid doses
    - Clonidine initial dosage of 0.025-0.05 mg 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).
    - 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)
  - If planning discontinuation, these medications must be tapered

#### Side Effects

- Sedation 
- Irritability 
- Headache 
- Bradycardia 
- Hypotension – monitor blood pressure and heart rate***

- **Atomoxetine**
  - Initial liquid dose of 0.5 mg/kg/day with a maximum of 1.6 mg/kg/day (Kratochvil 2009)

#### Side Effects

- Mood Liability 
- Decreased appetite 
- Sleepiness 
- Abdominal Pain

* 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 3rd 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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<tr>
<th>Diagnosis</th>
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<tbody>
<tr>
<td>Anxiety</td>
<td>Psychotherapeutic Trial ▪ Behavioral therapy or preschool CBT (Geller and March 2012) for a minimum of 12 weeks ▪ Parenting intervention for anxiety without mood disorder (Luby 2013)</td>
<td>Fluoxetine (last resort intervention) ▪ Initial low dose 2.5mg – 5mg to improve tolerability of SSRI (Fanton and Gleason 2009) ▪ Planned discontinuation after 6-9 months Side Effects ▪ Headache ▪ Gastric distress ▪ Insomnia or increased motor activity ▪ Behavioral activation /disinhibition may be more frequent in younger children and children with comorbid ADHD or CNS disorders (Sakolsky and Birmaher 2008) ▪ Black box warning: SSRIs potentiate the risk for suicidal thinking ▪ 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.</td>
<td>Sertraline (last resort intervention) ▪ Initial low dose of 5-10mg/day with range up to 25mg (Fanton and Gleason 2009) ▪ Planned discontinuation after 6-9 months Side Effects ▪ Headache ▪ Gastric distress ▪ Insomnia or increased motor activity ▪ Behavioral activation /disinhibition may be more frequent in younger children and children with comorbid ADHD or central nervous system disorders (Sakolsky and Birmaher 2008) ▪ Black box warning: SSRIs potentiate the risk for suicidal thinking ▪ 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.</td>
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## Diagnosis

### Autism Spectrum Disorder

**Diagnostic Assessment /Screening Tool**
- Child Autism Rating Scale

**1st Line Treatment**
- Psychotherapeutic Trial
  - Parent psychoeducation
  - Early intervention to address (Gleason 2007):
    - Language
    - Social development
    - Adaptive functioning
    - Reduction in repetitive behaviors
    - Aggression
    - Tantrums
    - Self injury
    - Hyperactivity
    - Anxiety and Mood Dysregulation (if significant comorbid problems, please refer to those disorders in this guideline)
- Sensory sensitivity
- Behavioral Therapy (Kaplan and McCracken 2012) Applied Behavioral Analysis (ABA) gold standard

**2nd Line Treatment**
- Irritability and Aggression
  - Risperidone
    - Initial liquid dose 0.1 – 1.5mg/day with a maximum dosage of 3mg/day
  - Side Effects
    - Metabolic Syndrome (weight gain)
    - Elevation of serum prolactin
    - 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)
    - Close monitoring of patients is essential

**3rd Line Treatment**
- Irritability and Aggression
  - Aripiprazole
    - 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.

**Hyperactivity**
- Methylphenidate
  - Initial liquid dose 1-5mg
  - Side Effects
    - The rate of intolerability in children with ASD is the double (18%) that of typically developing children with ADHD (Kaplan & McCracken 2012)
    - Family/child history of heart condition
    - Loss of appetite - severely underweight (3rd percentile)
    - Stomach and/or head aches
    - Irritability
    - Increased blood pressure and pulse
    - Agitation
    - Mood changes
    - Abnormal movements (Kaplan & McCracken 2012)
    - Rebound insomnia/sedation

**Alpha-Agonists**
- 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)

**Side Effects** (Kaplan and McCracken 2012)
- FDA indication for 6-17 years
- Good results in school aged population
- Sedation
- Weight gain
- Extrapyramidal symptoms
- Presyncope with unsteady gait (Owen 2009)

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<tr>
<td><strong>Autism Spectrum Disorder</strong></td>
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<td>Repetitive Behaviors</td>
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<td></td>
<td>Fluoxetine (last resort intervention for severe symptoms)</td>
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<td>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)</td>
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<td></td>
<td>• 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)</td>
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<td></td>
<td>• Planned discontinuation after 6-12 months</td>
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<td></td>
<td>• Not tested on children younger than 5 years</td>
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<td></td>
<td>Side Effects:</td>
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<tr>
<td></td>
<td>• Headache</td>
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<td>• Gastric distress</td>
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<td></td>
<td>• Insomnia/ increased motor activity</td>
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<td></td>
<td>• 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)</td>
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<td>• Black box warning for all SSRIs potentiate the risk for suicidal thinking</td>
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### 4th Line Treatment

**Hyperactivity**

- Atomoxetine
  - Initial liquid dose of 0.5 mg/kg/day with a maximum of 1.6 mg/kg/day (Kratochvil 2009)

**Side Effects**

- Mood Liability
- Decreased appetite
- Sleepiness
- Abdominal Pain

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<th>3&lt;sup&gt;rd&lt;/sup&gt; Line Treatment</th>
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<tr>
<td>Bipolar</td>
<td>Psychotherapeutic Trial</td>
<td>Risperidone</td>
<td>Aripiprazole (Oh et al. 2013)</td>
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<tr>
<td></td>
<td>▪ Parent Child Interaction</td>
<td>▪ Initial liquid dose 0.1 – 1.5mg/day (Kaplan &amp; McCracken 2012)</td>
<td>▪ 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.</td>
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<td></td>
<td>Therapy (PCIT) (Luby 2013)</td>
<td>Side Effects</td>
<td>Side Effects</td>
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<tr>
<td></td>
<td>Note: address mania first, higher incidence of rapid cycling and mixed mania (Peruzzolo et al. 2013)</td>
<td>▪ Metabolic Syndrome</td>
<td>▪ Good results in school aged population but no preschool data</td>
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<td></td>
<td></td>
<td>▪ Extrapyramidal side effects</td>
<td>▪ Weight gain/Metabolic Syndrome</td>
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<td></td>
<td></td>
<td>▪ Elevation of serum prolactin</td>
<td>▪ Akathisia</td>
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<td>▪ Akathisia</td>
<td>▪ Extrapiramidal symptoms</td>
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<td></td>
<td>▪ Good treatment effects and comparatively mild side-effects to other atypical antipsychotics (Oh et al 2013)</td>
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<td>Quetiapine</td>
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<td>▪ 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)</td>
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<td></td>
<td></td>
<td>Side Effects</td>
<td>Side Effects</td>
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<tr>
<td></td>
<td></td>
<td>▪ Sedation</td>
<td>▪ Metabolic Syndrome/ significant weight gain</td>
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<td>▪ No extrapyramidal side effects</td>
<td>▪ No elevation of serum prolactin</td>
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| **Depression** | Psychotherapeutic Trial  
- Psychotherapeutic Treatment modalities that address the parent-child relationship such as Parent Child Interaction Therapy-Emotion Development (PCIT-ED)(Lenze et al 2011) | Fluoxetine (last resort intervention) (Hetrick et al 2012)  
- Suggested initial liquid dose 0.5-2mg/day to minimize side effects.  
- 5-8mg/day effective treatment dose for this age group (Gleason 2007)  
- Planned discontinuation after 9 months at therapeutic dose (Gleason 2007) |  
- Clinical experience suggests other SSRIs such as Citalopram and Escitalopram may be easier for preschool children to tolerate. However, with Citalopram prolonged QT intervals at dosages greater than 40mg need to be considered. |
| **Disruptive Behavior Disorder (DBD) and Aggression** | Psychotherapeutic Trial  
- Preschool CBT  
- Parent Child Interaction Therapy (PCIT), Incredible Years Program, Collaborative Problem Solving etc. (Luby 2006)  
- Infant/Toddler Parent Programs i.e. Child Parent Interactive Therapy  
- Classroom-Based Interventions Token Reward Systems | Disruptive/Aggressive Behavior plus any other major mental illness - see that category **Aggression**  
- Anti psychotics are often used to augment psychotherapy. For severe aggression in preschool age children, an atypical antipsychotic can be prescribed (Lohr and Honaker 2013)  
- Metabolic Syndrome  
- Extrapyramidal side effects  
- Elevation of serum prolactin |  |

Note: Treat the co-morbid disorders contributing to disruptive behavior first  
- Eyberg Child Behavior Inventory (ECBI)
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<tr>
<td>Obsessive Compulsive Disorder (OCD)</td>
<td>Psychotherapeutic Trial&lt;br&gt;▪ CBT using exposure and response prevention techniques and involving parents is recommended (Whiteside et al 2012)</td>
<td>Fluoxetine and Sertraline (last resort interventions)&lt;br&gt;▪ Insufficient evidence to recommend one medication over the other&lt;br&gt;▪ Fluoxetine - initial low dose 2.5mg – 5mg to improve tolerability of SSRI (Fanton and Gleason 2009)&lt;br&gt;▪ Sertraline – initial low dose of 5-10mg/day with range up to 25mg (Fanton and Gleason 2009)&lt;br&gt;▪ Recommended discontinuation after 6-8 months (Coskun and Zoroglu 2009)</td>
<td>Side Effects&lt;br&gt;▪ Has been approved by the Food and Drug Administration (FDA) for the treatment of OCD in children age 7 and up (Rockhill 2010)&lt;br&gt;▪ 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 severe OCD in preschool age children. Side effects, particularly behavioral activation/disinhibition, are concerning among the 0-5 population. (Coskun and Zoroglu 2009)&lt;br&gt;▪ Decreased appetite and weight loss&lt;br&gt;▪ Sleep disturbance&lt;br&gt;▪ Headache&lt;br&gt;▪ Abdominal pain&lt;br&gt;▪ 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.&lt;br&gt;▪ Given the sensitivity to side effects in the young child population, tapering is recommended</td>
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| PTSD             | Psychotherapeutic Trial  
▪ Child-parent psychotherapy (CPP) for a 6 month trial (Gleason et al., 2007) or preschool CBT for minimum of 12 weeks (Cohen 2003) | 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. | Alpha-agonist (Clonidine)  
▪ Clonidine initial dosage of 0.025-0.05mg up to 0.1 mg/day at bedtime (Ming 2008) (Ingrassia 2005)  
▪ Short term use, 1 month maximum before reassessment  
Side Effects (Pelayo and Yuen 2012)  
▪ Respiratory depression  
▪ Hypotension  
▪ Bradycardia  
▪ Irritability  
▪ Anticholinergic effects (e.g. dry mouth)  
▪ REM suppression  
▪ Parent education about safe administration and monitoring |