Psychotropic Medication Review Parameters for Foster Children

Introduction and General Principles

The use of psychotropic medications by children is an issue confronting parents, other caregivers, and health care professionals across the United States. Foster children, in particular, have multiple needs, including those related to emotional or psychological stress. Foster children may reside in areas of the state where mental health professionals such as child psychiatrists are not readily available. Similarly, caregivers and health providers may be faced with critical situations that require immediate decisions about the care to be delivered. For these and other reasons, a need exists for treatment guidelines and review parameters regarding the appropriate use of psychotropic medications in foster children.

Because of the complex issues involved in the lives of foster children, it is important that a comprehensive evaluation be performed before beginning treatment for a mental or behavioral disorder. Except in the case of an emergency, a child should receive a thorough health history, psychosocial assessment, mental status exam, and physical exam before the prescribing of psychotropic medication. The physical assessment should be performed by a physician or another healthcare professional qualified to perform such an assessment. It is recognized that in some situations, it may be in the best interest of the child to prescribe psychotropic medications before a physical exam can actually be performed. In these situations, a thorough health history should be performed to assess for significant medical disorders and past response to medications, and a physical evaluation should be performed as soon as possible. The mental health assessment should be performed by an appropriately qualified mental health professional with experience in providing care to children. The child's symptoms and functioning should be assessed across multiple domains, and the assessment should be developmentally appropriate. It is very important that information about the child's history and current functioning be made available to the treating physician in a timely manner, either through an adult who is well-informed about the child or through a comprehensive medical record.

The role of nonpharmacological interventions should be considered before beginning a psychotropic medication, except in urgent situations such as suicidal ideation, psychosis, self injurious behavior, or physical aggression that is acutely dangerous to others. Given the unusual stress and change in environmental circumstances associated with being a foster child, counseling or psychotherapy should generally begin before or concurrent with prescription of a psychotropic medication. Patient and caregiver education about the mental disorder, treatment options (nonpharmacological and pharmacological), treatment expectations, and potential side effects should occur before and during the prescription of psychotropic medications.

It is recognized that many psychotropic medications do not have Food and Drug Administration (FDA) approved labeling for use in children. The FDA has a statutory mandate to determine whether pharmaceutical company sponsored research indicates that

a medication is safe and effective for those indications in which it has been studied by the manufacturer. The FDA also assures that information in the approved product labeling is accurate, and limits the manufacturer's marketing to the information contained in the approved labeling. ***The FDA does not regulate physician and other health provider practice. In fact, the FDA has stated that it does "not limit the manner in which a practitioner may prescribe an approved drug." Studies and expert clinical experience often support the use of a medication for an "off-label" use.*** Physicians should utilize the available evidence, expert opinion, their own clinical experience, and exercise their clinical judgment in prescribing what they feel is best for each individual patient.

General principles regarding the use of psychotropic medications in children include:

- A DSM-IV psychiatric diagnosis should be made before the prescribing of psychotropic medications.
- Clearly defined target goals for the use of psychotropic medications should be identified and documented in the medical record at the time of or before beginning treatment with a psychotropic medication. These target goals should be assessed at each clinic visit with the child and caregiver. Whenever possible, recognized clinical rating scales (either clinician, patient, or caregiver assessed, as appropriate) should be used to quantify the response of the child's target symptoms to treatment.
- During the prescription of psychotropic medication, the presence or absence of medication side effects should be documented in the child's medical record at each visit.
- Appropriate monitoring of indices such as height, weight, blood pressure, or other laboratory findings should be documented.
- Monotherapy regimens for a given disorder or specific target symptoms should usually be tried before polypharmacy regimens;
- Doses should usually be started low and titrated carefully as needed;
- Only one medication should be changed at a time;
- The frequency of clinician follow-up with the patient should be appropriate for the severity of the child's condition and adequate to monitor response to treatment, including: symptoms, behavior, function, and potential medication side effects.
- If the prescribing clinician is not a child psychiatrist, referral to or consultation with a psychiatrist should occur if the child's clinical status has not experienced meaningful improvement within a reasonable timeframe.
- Before adding additional psychotropic medications to a regimen, the child should be assessed for adequate medication adherence, accuracy of the diagnosis, the occurrence of comorbid disorders (including substance abuse and general medical disorders), and the influence of psychosocial stressors.
- If a medication is being used in a child for a primary target symptom of aggression associated with a DSM-IV nonpsychotic diagnosis (e.g., conduct disorder, oppositional defiant disorder, intermittent explosive disorder), and the behavior disturbance has been in remission for six months, then serious consideration should be given to slow tapering and discontinuation of the medication. If the medication is continued in this situation, the necessity for continued treatment should be evaluated at a minimum of every six months.

Review Criteria

The following situations indicate a need for further review of a patient's case. These parameters do not necessarily indicate that treatment is inappropriate, but they do indicate a need for further review.

For a child being prescribed a psychotropic medication, any of the following suggests the need for additional review of a patient's clinical status:

1) Absence of a thorough assessment of DSM-IV diagnosis in the child's medical record.

2) Five (5) or more psychotropic medications prescribed concomitantly.

3) Prescribing of:
   a) Two (2) or more concomitant antidepressants
   b) Two (2) or more concomitant antipsychotic medications
   c) Two (2) or more concomitant stimulant medications[1]
   d) Three (3) or more concomitant mood stabilizer medications

4) The prescribed psychotropic medication is not consistent with the patient's diagnosis or the patient's target symptoms (i.e., specific symptoms observed in a child that are associated with a mental disorder, and that usually respond to the medication being prescribed).

5) Psychotropic polypharmacy for a given mental disorder is prescribed before utilizing psychotropic monotherapy.

6) The psychotropic medication dose exceeds usually recommended doses.[2]

7) Psychotropic medications are prescribed for children of very young age, including children receiving the following medications with an age of:

   - Antidepressants: Less than four (4) years of age
   - Antipsychotics: Less than four (4) years of age
   - Psychostimulants: Less than three (3) years of age

8) Prescribing by a primary care provider for a diagnosis **<u>other</u>** than the following (unless recommended by a psychiatrist consultant):

   - Attention Deficit Hyperactive Disorder (ADHD)
   - Uncomplicated anxiety disorders
   - Uncomplicated depression

Notes:

(1) The prescription of a long-acting stimulant and an immediate release stimulant of the same chemical entity (e.g., methylphenidate) does not constitute concomitant prescribing.

(2) Usual recommended maximum doses of common psychotropic medications*

**Note: These doses represent usual daily maximum doses. Individual patient circumstances may dictate the need for the use of higher doses in specific patients. In these cases, careful documentation of the rationale for the higher dose should occur, and careful monitoring and documentation of response to treatment should be observed.*

Antidepressants/Anxiolytics	**Maximum Dose per Day**	
	Children	***Adolescents***
Citalopram	40 mg	40 mg
Escitalopram	20 mg	20 mg
Fluvoxamine[(2)]	200 mg	200 mg
Fluoxetine[(1, 2)]	20 mg	40 mg
Paroxetine	30 mg	40 mg
Sertraline[(2)]	200 mg	200 mg
Venlafaxine	3 mg/kg/d	225 mg

(1) Has FDA approved labeling for treatment of depression in children.
(2) Has FDA approved labeling for treatment of anxiety disorders in children.

Antipsychotics	**Maximum Dose per Day**	
	Children	***Adolescents***
Aripiprazole	15 mg	30 mg
Clozapine	300 mg	600 mg
Haloperidol	10 mg	20 mg
Olanzapine	12.5 mg	20 mg
Quetiapine	No data	600 mg
Risperidone	4 mg	6 mg
Ziprasidone	No data	180 mg

ADHD Medications	Maximum Dose per Day	
	Children	*Adolescents*
Amphetamine (Mixed amphetamine salts or dextroamphetamine)	40 mg	40 mg
Atomoxetine	1.8 mg/kg/d	100 mg
Bupropion	6 mg/kg/d	400 mg
Clonidine	0.4 mg	0.4 mg
Guanfacine	4 mg	4 mg
Imipramine	5 mg/kg/day	300 mg
Methylphenidate	60 mg	65 mg
Nortriptyline	3 mg/kg/day	150 mg

Mood Stabilizers	Maximum Dose per Day	
	Children	*Adolescents*
Carbamazepine(1)	7 mg/kg/day	(Max Cs: 12 mcg/mL
Lamotrigine	15mg/kg/d (200 mg)	200 mg
Lithium(1)	30 mg/kg/day	(Max Cs: 1.2 mEq/L)
Valproic acid(1) (Divalproex)	20 mg/kg/day	(Max Cs: 125 mcg/ml)

(1) Maximum daily dose typically determined by drug serum concentration (Cs) and individual patient tolerability.

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References:

21 CFR Part 201. Specific Requirements on Content and Format of Labeling for Human Prescription Drugs: Revision of "Pediatric Use" Subsection in the Labeling; Final Rule, Federal Register: December 13, 1994.

Advisory Committee on Psychotropic Medications. *The use of psychotropic medications for children and youth in the Texas foster care system.* Texas Department of Family and Protective Services, September 1, 2004.

Children and Adolescents' Psychoactive Medication Workgroup. *Psychoactive medication for children and adolescents: Orientation for Parents, Guardians, and Others.* Massachusetts Department of Mental Health, Boston, July 2003. http://www.mass.gov/dmh/publications/PsychoactiveBooklet.pdf (accessed October 13, 2004)

Emslie GJ, Hughes CW, Crismon ML, Lopez M, Pliszka S, Toprac MG, Boemer C. A feasibility study of the childhood depression medication algorithm: the Texas Children's Medication Algorithm Project (CMAP). *J Am Acad Child Adolesc Psychiatry* 2004;43:519-27.

Greenhill LL, AACAP Work Group on Quality Issues. Practice parameter for the use of stimulant medications in the treatment of children, adolescents, and adults. *J Am Acad Child Adolesc Psychiatr* 2002;41(supplement):26S-49S.

Jensen PS, MacIntyre JC, Pappadopulos EA, eds. *Treatment recommendations for the use of antipsychotic medications for aggressive youth (TRAAY) - pocket reference guide for clinicians in child and adolescent psychiatry*. 2004. New York State Office of Mental Health and Center for the Advancement of Children's Mental Health at Columbia University, Department of Child and Adolescent Psychiatry, New York, NY; 38 pp.

Kowatch RA, DelBello MP. The use of mood stabilizers and atypical antipsychotics in children and adolescents with bipolar disorders. *CNS Spectrum* 2003;8:273-80.

Kutcher SP. *Practical child & adolescent psychopharmacology*. Cambridge University Press, Cambridge, UK, 2002: 457 pp.

Pappadopulos E, MacIntyre JC, Crismon ML, Findling RL, Malone RP, Derivan A, Schooler N, Sikich L, Greenhill L, Schur SB, Felton C, Kanzler H, Rube D, Sverd J, Finnerty M, Ketner S, Siennick SE, Jensen PS. Treatment recommendations for the use of antipsychotics for aggressive Youth (TRAAY): Part II. *J Am Acad Child Adolesc Psychiatry* 2003;42:145-61.

Patel NC, Crismon ML, Hoagwood K, Jensen PS. Unanswered questions regarding antipsychotic use in children and adolescents. *Jour Child & Adolesc Psychopharm* (in press).

Pavuluri MN, Henry DB, Devineni B, Carbray JA, Naylor MW, Janicak PG. A pharmacotherapy algorithm for stabilization and maintenance of pediatric bipolar disorder. *J Am Acad Child & Adolesc Psychiatry* 2004;43:859-67.

Pliszka SR. Non-stimulant treatment of attention-deficit hyperactivity disorder. *CNS Spectrums* 2003;8:253-58.

Pliszka SR, Lopez M, Crismon ML, Toprac M, Hughes CW, Emslie GJ, Boemer C. A feasibility study of the Children's Medication Algorithm Project (CMAP) algorithm for the treatment of ADHD. *J Am Acad Child Adolesc Psychiatry* 2003;42:279-87.

Prescribing psychoactive medications for children and adolescents: Policy Statement, American Academy of Child and Adolescent Psychiatry,, Revised and approved by the Council, September 20, 2001, http://.aacap.org/publications/policy/ps41.htm (accessed October 12, 2004).

Psychiatric care of children in the foster care system: Policy Statement, American Academy of Child and Adolescent Psychiatry, Revised and approved by the Council, September 20, 2001, http://www.aacap.org/publications/policy/ps45.htm (accessed October 12, 2004).

Scahill L, Martin A. Pediatric psychopharmacology II. General principles, specific drug treatments, and clinical practice. In: Lewis M (ed.). *Child and adolescent psychiatry: A comprehensive textbook.* Lippincott Williams & Wilkins, Philadelphia, 2002: 951-74.

Schur SB, Sikich L, Findling RL; Malone RP, Crismon ML, Derivan, A, MacIntyre II JC, Pappadopulos E, Greenhill L, Schooler N, Van Orden K, Jensen PS. Treatments for aggression in children and adolescents: a review. *J Am Acad Child Adolesc Psychiatry* 2003;42:132-44.

Wagner KD. Treatment of childhood and adolescent disorders. In: Schaztzberg AF, Nemeroff CB (eds). *Textbook of psychopharmacology, 3rd. Ed*. American Psychiatric Publishing, Washington, DC, 2004: 949-1007.

When to seek referral or consultation with a child and adolescent psychiatrist: Recommendations for pediatricians, family practitioners, psychiatrists, and non-physician mental health practitioners. American Academy of Child and Adolescent Psychiatry, Copyright 2004. http://www.aacap.org/clinical/whentoseek.htm (accessed October 12, 2004).