PSYCHOTROPIC MEDICATION UTILIZATION PARAMETERS FOR CHILDREN AND YOUTH IN FOSTER CARE

Introduction and General Principles

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Adapted for New Mexico from with permission from the Texas Department of Family and Protective Services

The use of psychotropic medications by children and youth is an issue confronting parents, other caregivers, and health care professionals across the United States. Children and youth in foster care, in particular, have multiple needs, including those related to emotional or psychological stress. They typically have experienced abusive, neglectful, serial or chaotic caretaking environments. Birth family history is often not available. These children often present with a fluidity of different symptoms over time reflective of past traumatic events that may mimic many psychiatric disorders and result in difficulties with attachment, mood regulation, behavioral control, and other areas of functioning.

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 prescribing a 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 emergency 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. A thorough psychosocial assessment should be performed by an appropriately qualified mental health clinician (midlevel, masters or doctoral level), a general psychiatrist or child psychiatrist, or a primary care physician with experience in providing mental health care to children and youth. The child's symptoms and functioning should be assessed across multiple domains, and the assessment should be developmentally age appropriate. It is very important that information about the child's history, including history of trauma 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. Moreover, it is critical to meet the individual needs of patients and their families in a culturally competent manner. This indicates a need to address communication issues as well as differences in perspective on issues such as behavior and mental functioning. Interpretation of clinical symptoms and decisions concerning treatment should, whenever possible, be informed by the child's developmental history of trauma, neglect or abuse and the timing of these stressors. In general, optimal outcomes are achieved with well coordinated team-based care with members of different professions (e.g., child psychiatrist, child psychologist, social worker, primary care physician, etc.) each contributing their particular expertise to the treatment plan and follow-up. Additionally, at present there are no biomarkers to assist with the diagnosis of mental disorders, and imaging (e.g., MRI) and other tests (e.g., EEG are not generally helpful in making a clinical diagnosis of a mental disorder.

The role of interventions other than pharmacological should be considered before beginning a psychotropic medication, except in urgent situations such as suicidal ideation, psychosis self-injurious behavior, physical aggression that is acutely dangerous to others, or severe impulsivity endangering the child or others; when there is marked disturbance of psychophysiological functioning (such as profound sleep disturbance), or when the child shows marked anxiety, isolation or withdrawal. Given the history of trauma, unusual stress and

change in environmental circumstances associated with being a child in foster care, psychotherapy should generally begin before or concurrent with prescription of a psychotropic medication. Referral for trauma-informed, evidence-based psychotherapy should be considered when available and appropriate. Equally important, the role of the health care provider and the health care environment's potential to exacerbate a child's symptoms, given their respective trauma history, should be considered and minimized. It is critical to consider the role that transitions may play in the presentation of the child's symptomatology. It is common for children to manifest exacerbation or even sudden improvements ("honeymooning") in their presentation in the context of changing from one household or level of care to another. Baseline may not be clear until adjustment to the new environment is established.

Patient and caregiver education should be provided about the condition to be treated, treatment options (non-pharmacological and pharmacological), treatment expectations, and potential side effects that may occur 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 that are listed in the approved product labeling. The FDA 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 is best for each individual patient. To that end, clear documentation of the physician's rationale in the medical record facilitates continuity of care and minimizes misinterpretation.

Role of Primary Care Providers

Primary care providers play a valuable role in the care of youth with mental disorders. They are the clinicians most likely to initially interact with children who are in distress due to an emotional or psychiatric disorder, and they may also provide ongoing psychotropic medication management and care coordination due to lack of availability of child psychiatrists or other mental health clinicians.

Primary care clinicians should screen children for potential mental disorders, and they should be able to diagnose and treat relatively straightforward situations such as uncomplicated ADHD, anxiety, or depression. Primary care providers can provide advice to youth in foster care and their care givers about handling feelings and behaviors, recognizing the need for help, making decisions regarding healthy life styles, and the available treatments for childhood mental disorders. As always, consideration should be given regarding the need for referral for counseling, psychotherapy, or behavioral therapy. Short courses and intensive skills oriented seminars and phone consultation with child psychiatrists may be beneficial in assisting primary care clinicians in caring for children with mental disorders. In addition, the American

Academy of Pediatrics has recently provided a policy statement ("Health Care Issues for Children and Adolescents in Foster Care and Kinship Care") which can be found at: http://pediatrics.aappublications org/con- tent/136/4/e1131

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

- A DSM-5 psychiatric diagnosis should be made before the prescribing of psychotropic medications. Bear in mind that trauma response is "the great imitator" when it comes to this population. Traumatic events have varying consequences at differing developmental ages. The effects of chronic trauma may look quite different than those of more discrete trauma. Consequently, trauma symptoms may be quite variable and indistinguishable from symptoms of ADHD, Anxiety disorders, ODD, Conduct disorder, Depressive conditions and Bipolar Disorder to name a few.

- Clearly defined target symptoms and treatment 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 symptoms and treatment goals should be assessed at each clinic visit with the child and caregiver in a culturally and linguistically appropriate manner. Whenever possible, standardized clinical rating scales (clinician, patient, primary caregiver, teachers, and other care providers) or other measures should be used to quantify the response of the child's target symptoms to treatment and the progress made toward treatment goals.
- In making a decision regarding whether to prescribe a psychotropic medication in a specific child, the clinician should carefully consider potential side effects, including those that are uncommon but potentially severe, and evaluate the overall benefit to risk ratio of pharmacotherapy.
- Except in the case of an emergency, informed consent should be obtained from the appropriate party(s) before beginning psychotropic medication. Informed consent to treatment with psychotropic medication entails diagnosis, expected benefits and risks of treatment, including common side effects, discussion of laboratory findings, and uncommon but potentially severe adverse events. Alternative treatments, the risks associated with no treatment, and the overall potential benefit to risk ratio of treatment should be discussed.
- Whenever possible, trauma-informed, evidence-based psychotherapy, should begin before or concurrent with the prescription of psychotropic medication.
- Before starting psychopharmacological treatment in preschool-aged children an emphasis should be placed on treatment with non-psychopharmacological interventions. Assessment of parent functioning and mental health needs, in addition to training parents in evidence-based behavior management can also reduce the need for the use of medication.
- Medication management should be collaborative. Youth, as well as caregivers, should be involved in decision-making about treatment, in accordance with their developmental level. Parents providing informed consent should be engaged, and where applicable, other caregivers, family, and child related agencies should be involved.
- 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 laboratory findings should

be documented, including standardized scales such as the Abnormal Involuntary Movement Scale (AIMS).

- Monotherapy regimens for a given disorder or specific target symptoms should usually be tried before polypharmacy regimens. While the goal is to use as few psychotropic medications as can be used to appropriately address the child's clinical status, it is recognized that the presence of psychiatric comorbidities may affect the psychotropic medications that are prescribed. When polypharmacy regimens are needed, the addition of medications should occur in a systematic orderly process, accompanied by on-going monitoring, evaluation, and documentation. The goal remains to minimize polypharmacy while maximizing therapeutic outcomes.
- Medications should be initiated at the lower end of the recommended dose range and titrated carefully as needed.
- Only one medication should be changed at a time, unless a clinically appropriate reason to do otherwise is documented in the medical record. (Note: starting a new medication and beginning the dose taper of a current medication is considered one medication change).
- The use of prn or "as needed" prescriptions is discouraged. If they are used, the situation indicating need for the administration of a prn medication should be clearly indicated as well as the maximum dosage in a 24 hour period and in a week. The frequency of administration should be monitored to assure that these do not become regularly scheduled medications unless clinically indicated.
- The frequency of clinician follow-up 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. At a minimum, a child receiving psychotropic medication should be seen by the clinician at least once every ninety days.
- The potential for emergent suicidality should be carefully evaluated and monitored, particularly in depressed children and adolescents as well as those initiating antidepressants, those having a history of suicidal behavior or deliberate self-harm and those with a history of anxiety or substance abuse disorders.
- If the prescribing clinician is not a child psychiatrist, referral to or consultation with a child psychiatrist, or a general psychiatrist with significant experience in treating children, should occur if the child's clinical status has not shown meaningful improvement within a timeframe that is appropriate for the child's diagnosis and the medication regimen being used.
- Before adding additional psychotropic medications to a regimen, the child should be assessed for adequate medication adherence, appropriateness of medication daily dosage, 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 has not resulted in improvement in a child's target symptoms (or rating scale score), discontinue that medication rather than adding a second medication to it.
- If a medication is being used in a child for a primary target symptom of aggression associated with a DSM-5 non-psychotic 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 and

documented in the medical record at a minimum of every six months.

- The clinician should clearly document care provided in the child's medical record, including history, mental status assessment, physical findings (when relevant), impressions, rationale for medications prescribed, adequate laboratory monitoring specific to the drug(s) prescribed at intervals required specific to the prescribed drug and potential known risks, medication response, presence or absence of side effects, treatment plan, and intended use of prescribed medications.

Use of Psychotropic Medication in Preschool Aged Children

The use of psychotropic medication in young children of preschool ages is a practice that is limited by the lack of evidence available for use of these agents in this age group. The Preschool Psychopharmacology Working Group (PPWG) published guidelines (Gleason, 2007) summarizing available evidence for use of psychotropic medications in this age group. The PPWG was established in response to the clinical needs of preschoolers being treated with psychotropic agents and the absence of systematic practice guidelines for this age group, with its central purpose to attempt to promote an evidence-based, informed, and clinically sound approach when considering medications in preschool-aged children.

The PPWG guidelines emphasize consideration of multiple different factors when deciding on whether to prescribe psychotropic medications to preschool-aged children. Such factors include the assessment and diagnostic methods utilized in evaluating the child for psychiatric symptoms/illness, the current state of knowledge regarding the impact of psychotropic medication use on childhood neurodevelopmental processes, the regulatory and ethical contexts of use of psychotropic medications in small children (including available safety information and FDA status), and the existing evidence base for use of psychotropic medication in preschool aged children.

The publication includes specific guidelines and algorithm schematics developed by the PPWG to help guide treatment decisions for a number of psychiatric disorders that may present in preschool-aged children, including Attention-Deficit Hyperactivity Disorder, Disruptive Behavioral Disorders, Major Depressive Disorder, Bipolar Disorder, Anxiety Disorders, Post-Traumatic Stress Disorder, Obsessive-Compulsive Disorder, Pervasive Developmental Disorders, and Primary Sleep Disorders. The working group's key points and guidelines are similar to the general principles regarding the use of psychotropic medication in children already detailed in this paper. However, the working group's algorithms put more emphasis on treating preschool-aged children with non-psychopharmacological interventions (for up to 12 weeks) before starting psychopharmacological treatment, in an effort to be very cautious in introducing psychopharmacological interventions to rapidly developing preschoolers.

The working group also emphasizes the need to assess parent functioning and mental health needs, in addition to training parents in evidence-based behavior management, since parent behavior and functioning can have a large impact on behavior and symptoms in preschool-aged children.

Levels of Warnings Associated with Medication Adverse Effects

All medications including psychotropic medications have potential side effects. Clinicians should be familiar with all medication adverse effects, including boxed warnings, in

order to appropriately monitor patients and minimize adverse effects. The medication tables that accompany this document include boxed warnings as well as other potential adverse effects. The list of potential adverse effects in the tables should not be considered exhaustive, and the clinician should consult the FDA approved product labeling and other reliable sources for information regarding medication adverse effects.

Adverse effects that are detected prior to marketing are included in the FDA approved product labeling provided by the manufacturers. These adverse effects are listed in the "Warnings and Precautions" section. The "Adverse Reactions" section of the product labeling outlines those adverse effects reported during clinical trials, as well as those discovered during post-marketing evaluation. Many other drug information resources also list common adverse effects and precautions for use with psychotropic medications.

At times, post-marketing evaluation detects critical adverse effects associated with significant morbidity and mortality. The FDA may require manufacturers to revise product labeling to indicate these critical adverse effects. If found to be particularly significant, these effects are demarcated by a box outlining the information at the very beginning of the product labeling, and are named boxed warnings, often termed Black Box Warnings. Boxed warnings are the strongest warning required by the FDA.

Medications, including psychotropic medications, are sometimes prescribed for indications (e.g., a disease or symptom) that has never received FDA approval. This can occur when a medication hasn't been studied or approved for a specific population (such as children) but has been shown to be safe and effective in a different population (such as adults), or when one medication in a class of drugs has FDA approval, but another medication in the same class does not. Clinicians should keep up to date with FDA approvals of psychotropic medications, and should follow recognized standards of care in their use of "off label" prescribing.

Medication Guides have been developed by the FDA to advise patients and caregivers regarding possible adverse effects associated with classes of medications, and include pre-cautions that they or healthcare providers may take while taking/prescribing certain classes of medications. The FDA requires that Medication Guides be issued with certain prescribed medications and biological products when the Agency determines that certain information is necessary to prevent serious adverse effects, that patient decision-making should be informed by information about a known serious side effect with a product, or when patient adherence to directions for the use of a product are essential to its effectiveness. If a Medication Guide has been developed for a certain class of medications, then one must be provided with every new prescription and refill of that medication.

Copies of the Medication Guides for psychotropic medications can be accessed on the FDA website at: http://www.fda.gov/Drugs/DrugSafety/ ucm085729.htm

Usual Recommended Doses of Common Psychotropic Medications

The attached medication charts are intended to reflect usual doses and brief medication information for commonly used psychotropic medications. The tables contain two columns for maximum recommended doses in children and adolescents – the maximum recommended in the FDA approved product labeling, and the maximum recommended in medical and pharmacological literature sources.

The tables are intended to serve as a resource for clinicians. The tables are not intended to serve as comprehensive drug information references or a substitute for sound clinical judgment in the care of individual patients. 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 performed. If the use of higher medication doses does not result in improvement in the patient's clinical status within a reasonable time period (e.g., 2-4 weeks), then the dosage should be decreased and other treatment options considered.

Not all medications prescribed by clinicians for psychiatric diagnoses in children and adolescents are included in the following tables. However, in general, medications not listed do not have adequate efficacy and safety information available to support a usual maximum dose recommendation.

See attached Psychotropic Medication Tables.