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Recommendations about the Use of Psychotropic Medications for Children and Adolescents Involved in Child-Serving Systems

Executive Summary

The American Academy of Child and Adolescent Psychiatry (AACAP) recognizes that there are current concerns about psychotropic prescribing practices for children and adolescents, especially involving those in foster care. This document is intended to promote safety and quality in mental health treatment, with particular attention to the appropriate use of psychotropic medication in children and adolescents in child-serving systems. Our recommendations apply to all children and adolescents, including those living in their family homes, foster care, and other out-of-home settings.

The decision to prescribe psychotropic medication is integrally linked to the entire process of mental health treatment. An overarching principle is that the use of psychotropic medication for children and adolescents should be part of holistic and collaborative mental health treatment. This involves a commitment to the biopsychosocial perspective, trauma-informed care principles, and system of care values and principles. Of particular importance is the need for prescribers and other professionals to provide care that is individualized, family-driven, and youth-guided, with recognition that collaborating with children and families is both an ethical and a pragmatic imperative. Such quality rests not only on important technical skills but also on strong therapeutic relationships, a biopsychosocial perspective (Engel, 1980), and commitment to both trauma-informed care principles (Fallot, 2009) and system of care principles (Pires, 2011; Pires, 2014).

When indicated, psychotropic medication needs to be prescribed according to the practice parameter developed by AACAP in 2009, and its use should be monitored by the prescriber and family/guardian and subject to oversight by relevant child-serving systems. Psychotropic medication should be provided in conjunction with evidence-based psychosocial interventions, except in the most uncomplicated situations when the use of medication alone may be considered.

States and communities need to have a clearly delineated process for medication monitoring and oversight because of concerning trends in the prescription of psychotropic medication. These include large variation in prescribing practices, increased use of these medications, particularly for youth in foster care, potential adverse effects, and cost implications. At the same time, given the pressing needs of many youth with complex psychiatric presentations, careful and judicious use of medication may be

appropriate despite limited empiric support. In light of these challenges, additional research into the effectiveness of psychosocial and psychotropic interventions is urgently needed.

The recommendations in this document fall into three general categories: clinical practice; psychotropic medication monitoring and oversight; and research.

Clinical Practice

1. Prescribers of psychotropic medication for children and adolescents, and others working with them and their families should adhere to a developmentally-informed biopsychosocial approach, trauma-informed care principles, and system of care principles.
2. When psychotropic medication is being considered, children and adolescents should receive a comprehensive behavioral health assessment.
3. Prescribers of psychotropic medication should actively engage and collaborate with children and adolescents and their families when they are referred for potential use of such medication.
4. Prescribers should actively engage and collaborate with other professionals and systems involved with the child and family.
5. All youth with complex behavioral needs, including youth in foster care, should receive a combination of evidence-based psychosocial interventions and psychotropic medication when indicated, not just psychotropic medication alone.
6. Clinical guidelines identified in the 2009 AACAP Practice Parameter, “Prescribing Psychotropic Medication to Children” should be implemented.
7. Prescribers should promote awareness of potential adverse effects and consistently monitor for such side effects over time.

Psychotropic Medication Monitoring and Oversight

8. Non-physician professionals working with youth should have knowledge of the guidelines in AACAP publications and other resource documents relevant to the use of psychotropic medication with youth.
9. Mental health agencies, child welfare, Medicaid agencies, and managed care organizations should collaborate to create systems to monitor, review, and inform practice patterns with psychotropic medications.
10. States and local agencies serving children in foster care should use the Best Principle Guideline in the 2005 AACAP Position Statement as the framework for developing formal medication monitoring and oversight programs.

11. Consultation programs should involve child and adolescents psychiatrists, who can offer technical assistance, second opinions, and case review when indicated.
12. Monitoring methods should entail a combination of approaches that include review of aggregate data on prescribing patterns, chart audits, and tracking of specific red flag markers.
13. Child and adolescent psychiatrists should participate in the development of monitoring and oversight standards in their state and community, and involved systems should actively support their involvement.
14. Psychotropic medication monitoring and oversight efforts should involve collaboration among state and local agencies as well as managed care organizations.
15. Systemic oversight of psychotropic medication prescribing should be pursued in a collegial manner that promotes the use of evidenced-informed practice.
16. Systems for medication review and for the approval or denial of psychotropic medication requests should be streamlined and efficient, to avoid unnecessary treatment delay or provider burden.
17. All stakeholders and child-serving systems responsible for youth with complex mental health needs should advocate for increased availability of evidence-based psychosocial interventions by qualified staff.

Research

18. Clinical research is necessary to investigate the most effective approaches to prevention, early intervention, and treatment of complex behavioral health needs of children and adolescents.

AACAP is committed to promoting prescribing practices that are safe and of high quality, and oversight and monitoring practices based on best practices that promote collaboration among systems and professionals. Child and adolescent psychiatrists can offer support, leadership and expertise with these important efforts.

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Introduction

The American Academy of Child and Adolescent Psychiatry (AACAP) recognizes that there are current concerns about psychotropic prescribing practices for children and adolescents, especially involving those in foster care. This document is intended to promote safety and quality in mental health treatment, with particular attention to the appropriate use of psychotropic medication in children and adolescents in child-serving systems. Our recommendations apply to all children and adolescents, including those living in their family homes, foster care, and other out-of-home settings.

An overarching principle is that the use of psychotropic medication for children and adolescents should be part of holistic and collaborative mental health treatment. Such quality rests not only on important technical skills but also on strong therapeutic relationships, a biopsychosocial perspective[1], and commitment to both trauma-informed care principles [2] and system of care principles [3, 4].

In order to address the appropriate use of psychotropic medication for children and adolescents, AACAP has developed a number of resources. These include practice parameters, policy statements, and other documents that address related the following topics of relevance:

- [2003 AACAP Policy Statement on Psychiatric Diagnostic Evaluations](#) [5]
- [1997 AACAP Practice Parameter for the Psychiatric Assessment of Children and Adolescents](#) [6] (Currently being updated)
- [1997 AACAP Practice Parameter for the Psychiatric Assessment of Infants and Toddlers](#) [7] (Scheduled to be update)

Treatment in a System of Care

- [2013 AACAP Practice Parameter for Cultural Competence in Child and Adolescent Psychiatric Practice](#) [8]
- [2012 “A Guide for Community Child Serving Agencies on Psychotropic Medications for Children and Adolescents”](#) (2012 document developed in response to a request by the Center for Mental Health Services (CMHS))

within the federal Substance Abuse and Mental Health Services Administration (SAMHSA).[9]

- [2007 AACAP Practice Parameter on Child and Adolescent Mental Health Care in Community Systems of Care](#) [10]

Collaboration

- [2011 AACAP Policy Statement on Medical Homes for Children and Adolescents with Mental, Developmental, and Substance Abuse Disorders](#) [11]
- [2009 AACAP Policy Statement on Family and Youth Participation in Clinical Decision-Making](#) [12]
- [2008 AACAP Policy Statement on Collaboration with Pediatric Medical Professionals](#) [13]
- [2004 AACAP Policy Statement on Child and Adolescent Psychiatrists Role in Collaboration with Other Mental Health Professionals](#) [14]

Foster Care

- [2015 AACAP Practice Parameter for the Assessment and Management of Youth Involved With the Child Welfare System](#) [15]
- [2002 AACAP/Child Welfare League of America \(CWLA\) Foster Care Mental Health Subcommittee](#) [16]
- [2003 AACAP/CWLA Policy Statement on Mental Health Substance Abuse Use Screening/Assessment of Children in Foster Care](#) [17]
- [2001 AACAP Policy Statement on Psychiatric Care for Children in the Foster Care System](#) [18]

Prescribing Practices

- [2011 AACAP Practice Parameter for the Use of Atypical Antipsychotic Medications in Children and Adolescents](#) [19]
- [2009 AACAP Practice Parameter of the Use of Psychotropic Medication to Children](#) [20]
- [2001 AACAP Policy Statement on Prescribing Psychoactive Medications for Children and Adolescents](#) [21]
- [2006 AACAP Policy Statement on Evidence Based Practice](#) [22]
- [2005 AACAP Position Statement on Oversight of Psychotropic Medication Use for Children in State Custody: A Best Principles Guideline](#) [23]

Additional Documents – U.S. Government Accountability Office (GAO) documents drawing from AACAP’s 2005 [“Position Statement on Oversight of Psychotropic Medication for Children in State Custody”](#) [23].

AACAP's recommended standards in its 2005 "Position Statement on Oversight of Psychotropic Medication Use for Children in State Custody: A Best Principles Guideline" were incorporated by the U.S. Government Accountability Office (GAO) in two reports, "[Foster Children: HHS Guidance Could Help States Improve Oversight of Psychotropic Prescriptions](#)" and "[Foster Children: Additional Federal Guidance Could Help States Better Plan for Oversight of Psychotropic Medications Administered by Managed-Care Organizations](#)" [23-25]. For these GAO reports, two child and adolescent psychiatrist, who are AACAP members, served as contracted consultants.

Frameworks to Guide the Use of Psychotropic Medication

The use of psychotropic medication for children and adolescents and their families constitutes a significant medical decision. It should not be regarded as an isolated event, but rather understood as integrally linked to the entire process of mental health treatment. The prescribing and monitoring of psychotropic medication for youth should be guided by specific frameworks that promote comprehensive and ethically-based care. These frameworks involve a commitment to 1) the biopsychosocial perspective, 2) trauma-informed care principles, and 3) system of care principles.

Biopsychosocial Assessment and Treatment

As discussed in the AACAP "Guide for Community Child Serving Agencies on Psychotropic Medications for Children and Adolescents", psychotropic medications constitute only one component of a comprehensive biopsychosocial treatment plan. The term *biopsychosocial* refers to the three basic domains that impact every individual, to be addressed in evaluation and treatment – biological factors, psychological factors, and social factors [1, 9]:

- Biological factors include the entire range of psychiatric disorders, as well as the biological consequences of maltreatment and other trauma, possible exposure to drugs and alcohol in utero, nutrition, and overall physical health status.
- Psychological factors include the youth's emotional and behavioral functioning, strengths and interests, beliefs and values, social skills, and personal goals.
- Social factors, also referred to as the youth's context and social ecology, involve the youth's family, neighborhood, and community. It includes social strengths and protective factors (e.g., strong family relationships and strong community supports) as well social risk factors (e.g., poverty, trauma, and other childhood adversities).

The biopsychosocial approach creates the framework for a comprehensive, holistic approach to the child and family. When all three elements are carefully considered,

assessment is more complete and treatment is more comprehensive. The biopsychosocial perspective helps ensure that both biologically-based and psychosocial factors are part of treatment formulations and interventions.

Trauma-Informed Care Principles

Trauma-informed care and trauma-informed care principles constitute another important framework to guide the use of psychotropic medication, as well as other aspects of mental health treatment. Unfortunately, childhood trauma is exceedingly common: Two thirds of American youth have experienced a significant traumatic event by age 16, and more than one third have been exposed to multiple types of trauma [26]. Youth in child-serving systems, including child welfare and juvenile justice, have particularly high trauma exposure. In addition, trauma and especially maltreatment can result in significant disruptions in psychosocial development and health [26], with potential lifelong consequences [27]. Given these realities, and with the additional risk of inadvertent trauma on individuals induced by human service systems, there is clear need for trauma-informed care and trauma-informed principles. Trauma-informed care involves recognition of the prevalence and impact of trauma, and a commitment to minimize its effects and avoid additional traumatization. Trauma-informed principles guide the conduct of professionals, agencies, and systems, leading to positive relationships with youth and families and among involved professionals, which help prevent trauma and promote healing.

Child and adolescent psychiatrists and other mental health and human service professionals can promote positive outcomes for youth and families by implementing the following core trauma-informed principles [2]:

- Safety
- Trustworthiness
- Collaboration
- Choice
- Empowerment

A full commitment to trauma-informed care also entails a range of additional trauma-informed practices. Such practices include trauma screening for children and adolescents, and inquiry by the evaluator about a child's trauma-related experiences. Traumatic experiences include maltreatment, poverty, bullying, community violence, disrupted attachments, and other losses. Trauma-related inquiry should be pursued with the involvement of the parents or legal guardians as well as the child, so that it becomes a collaborative process. It is also essential to determine if the child is experiencing significant ongoing trauma. When trauma or trauma-related symptoms are present, immediate referrals should be made. Trauma-informed practices also include access to trauma treatment when needed, and ongoing collaboration among involved service providers, agencies, and systems.

The goal is for both practitioners and systems to be trauma-informed, implementing both trauma-informed principles and trauma-informed practices.

System of Care Principles

All providers and child-serving agencies are part of a system of care, whether or not this term is sufficiently appreciated and whether or not the system of care is comprehensive and well-coordinated. Children receiving privately insured mental health treatment, those on Medicaid receiving in-home treatment, and those involved in child welfare or juvenile justice are all part of a local system of care.

System of care principles can help guide an ethically-based and empowering experience for children and families. Services consistent with system of care principles [3, 4] are:

- Family-driven and youth-guided
- Home and community-based
- Strengths-based and individualized
- Culturally and linguistically competent
- Integrated across systems
- Connected to natural helping networks
- Data-driven and outcomes-oriented
- Public health-oriented, involving health promotion, prevention, and early intervention
- Trauma-informed (added in 2014)

Implementation of system of care principles can improve the safety and quality of psychotropic medication prescribing. For example:

- *Informed consent* and shared-decision making are consistent with family-driven and youth-guided care.
- *Screening and assessment* are consistent with a public health approach.
- The use of psychotropic medication with an indicated psychosocial intervention is consistent with *individualized care*.
- *Collaboration* among prescribers, professionals, and agencies is consistent with care that is integrated across systems, reflecting that medication prescribing is embedded in a broader, holistic, strength-based approach to care.
- *Monitoring of medication* is consistent with data-driven, outcomes-oriented care.

What Psychotropic Medication Can and Cannot Do

In recent years, there has been “increased public acceptance over the appropriateness of treating major psychiatric disorders with prescription

medications” [28]. In addition, there is a significant and expanding evidence base regarding the efficacy of psychotropic medication in the treatment of child and adolescent psychiatric disorders [20]. There is a clear role for psychotropic medication in the mental health treatment of children and adolescents “as part of a comprehensive treatment” [29]. In fact, some children with serious mental health challenges “would suffer serious consequences without such medication” [30].

However, medication has limitations as well. It is important to understand what psychotropic medication can and cannot reasonably be expected to accomplish.

What Psychotropic Medication Can Do

There is growing evidence that psychotropic medication can be helpful in the treatment of a range of child and adolescent psychiatric conditions [20]. Psychotropic medication can “level the physiological playing field” for a child or adolescent with a mental health disorder. This may involve decreasing hyperarousal, anxiety or depression, or ameliorating the cognitive distortions of psychosis. It may also involve increasing a child’s capacity to focus. In addressing impulsivity, psychostimulant medication can enable the child with the Combined Type of ADHD to exercise increased self-control in response to provocation or other distracting stimulation. One practical effect of increased physiological regulation gained through use of psychotropic medication is that some youth previously unable to benefit from psychotherapy and other mental health treatments can now do so.

What Psychotropic Medication Cannot Do

Psychotropic medication does not change a child’s past life experiences and the impact of these experiences on his or her view of the world. A young survivor of maltreatment who is angry and guarded does not become trusting simply as a result of medication use. Medication alone does not eliminate the residual psychological effects of maltreatment, and does not alter a child’s beliefs and values. Medication alone also does not provide the child with new coping skills, or restore the child’s sense of safety. These considerations reinforce the need for a biopsychosocial approach.

Research on Psychotropic Medication Use

Varying Cohorts of Youth under Study

A review of psychotropic medication use in youth can be approached from many different perspectives. For example, the cohort under study may involve any of the following groups of youth:

- All youth under the age of 21, regardless of type of insurance or place of residence.

- All youth on Medicaid, which includes those on Medicaid due to low income, disability, or child welfare involvement.
- Youth in child welfare, with particular focus on those in foster care.
- Youth receiving outpatient treatment from physicians in an office-based medical practice, involving psychiatrists and non-psychiatric physicians such as pediatricians and family practitioners.
- Youth medication use according to age – e.g., the distinction between children (0-13 years) and adolescents (14-20 years).
- Consideration of children under age 5 years as a separate group, and children under age 1 year.

Given the variability of the group under study, it can be difficult to compare statistics from different studies. It is therefore important to understand the specific group of children and adolescents under review, and under what circumstances.

Key Variables under Study

Specific trends that can be tracked related to psychotropic medication use in youth include the following:

- Rate of use of all psychotropic medications.
- Rate of use of specific classes of medication, including antipsychotics, antidepressants, psychostimulants, etc.
- Extent of use of multiple psychotropic medications at the same time. Referred to as polypharmacy, there are different thresholds for the number of concurrent psychotropic medications that constitute a concern.
- Extent of use of medications above recommended maximum dose levels.
- Frequency of use of effective psychosocial treatments in conjunction with use of psychotropic medication.
- Comparison of frequency of use of specific psychotropic medications or classes of medications in the same cohorts of youth in different geographic regions.
- Comparison of frequency of use of psychotropic medications over time by different types of prescribers: child and adolescent psychiatrists, non-psychiatric physicians, and other prescribers.
- Rates of side effects, especially more serious side effects such as weight gain or other metabolic side effects, as well as adequacy of prescriber monitoring for side effects

Concerns about psychotropic medication with youth receiving “too many,” “too much,” and “too young” have been identified primarily in relation to children in foster care. However, these variables – overall trends in prescribing over time and number of medications used, dosages used that exceed recommended guidelines, and age of child for which medications are used – are relevant for all youth. There is evidence that prescriptions of psychotropic medications to youth have been

increasing over at least the past 25 years, in some instances dramatically, as detailed below.

Trends in Psychotropic Medication Prescribing

Trends in Current National Studies Inclusive of a Broad Range of Youth

A recent study tracked mental health service use, including provision of psychotropic medication prescriptions, among children, adolescents, and adults seen by office-based physicians – both psychiatrists and primary care physicians in offices or community health centers – as part of outpatient treatment [31]. The period under study is 1995-2010, and the cohort includes individuals on private insurance, Medicaid, or Medicare. Key findings include the following:

- During the time period, office-based physicians saw an increasing number of children and adolescents for reasons related to mental health. These visits resulted in an increase in mental health diagnoses and an increase in psychotropic medication use.
- Psychotherapy visits increased especially for adolescents, but not for adults. The data captures only psychotherapy provided during the visit by the physician (primarily the psychiatrist), not mental health treatment provided elsewhere by other mental health professionals.
- Antipsychotics were the fastest growing class of psychotropic medications among young people, especially for the years, 2003-2010. Antipsychotic prescriptions grew most rapidly among by non-psychiatric physicians.
- The increase in antipsychotic use was most likely due to an increase in the use of this class of medication for aggression.
- The study does not capture those youth seen in community mental health centers and hospital outpatient mental health clinics, settings that may disproportionately serve youth from low income families.

The above information can be reviewed in light of an earlier study from 1987-1996 on the use of psychotropic medication by youth less than 18 years of age [32]. Using data from two nationally representative surveys, this earlier study found that the rate of prescriptions increased from 1.4 to 3.9 per 100 persons during the period under study. In particular, from 1987-1996 there was a four-fold increase in the rate of prescription of stimulant medications and a 3.3-fold increase in the rate of prescription of antidepressants.

Trends in Current Studies of Medication Use by Youth on Medicaid

A recent national study examined the prescribing patterns between 2004 and 2008 for youth ages 6-18 in Medicaid [33]. The study found increases in the use of second-generation antipsychotics (SGAs), often used in combination with other psychotropic medications. The use of SGAs concurrent with other psychotropic medication was not restricted to youth in foster care, or to those youth presumed to have the most severe or acute mental health needs:

- During the study period, there was a 22% overall increase in the use of SGAs. This increase is in contrast to the stable or declining use of other classes of psychotropic medication.
- Overall, 85% of the SGA use was concurrent with use of other psychotropic medication classes.
- The greatest use of SGA medication with other medication classes was not among youth in foster care but among youth who were Medicaid-eligible due to low income, were not hospitalized, and did not have comorbid ADHD or intellectual disability.
- Thus, use of concurrent SGA was found to be increasing disproportionately “among youth with less perceived comorbidity and impairment,” rather than among youth in foster care or those with serious mental illness in hospital settings. This pattern represents “a changing trend in prescribing practice that increasingly favors concurrent SGA use in less impaired youth.”
- An additional finding was that the concurrent prescribing of multiple psychotropic medications is more common among psychiatrists than primary care physicians.

Concerns about Children and Adolescents in Foster Care

Reasons for Concern

There are many reasons for the concern about medication prescribing for youth in foster care:

- Children in foster care constitute a highly vulnerable population, reflected in the documented history of maltreatment of each youth and the need for removal from the family of origin. They often have “emotional and behavioral problems that derail normal development, hinder healthy functioning, and impede the achievement of permanency... [29].
- Youth in foster care in general do not have the safety net of those living with their own families, and typically lack a well-resourced family to advocate actively for their needs.
- Youth in foster care may be subject to inappropriate prescribing practices – “too many,” “too much,” and “too young” – compared to youth not involved with child welfare.

- Psychotropic medication can have limited benefit or be ineffective when prescribed alone, without the combined use of an evidence-based psychosocial intervention.
- Psychotropic medications, especially SGAs and mood stabilizing medications, can have serious metabolic and other side effects.
- For children in foster care to be successful, the provision of safety and permanency is essential but not sufficient. There needs to be greater focus on promoting youth wellness, particularly social and emotional wellness [34]. The latter includes promoting the youth's attachments and other relationships, and a variety of social and life skills.

Evidence of Increased Vulnerabilities among Foster Care Youth

As a result of their adversities, youth in foster care may have more frequent and severe health challenges. The Government Accountability Office (GAO) notes that “children in foster care exhibit more numerous and serious medical conditions, including mental health conditions, than do other children” [30]. Such outcomes are consistent with the findings of the Adverse Childhood Experiences (ACE) study, which found that the more life adversities, including maltreatment, an individual experiences during childhood, the greater the odds of serious challenges over the lifespan involving physical health, mental health, and substance abuse [35].

The 2011 Government Accountability Office (GAO) Report on Youth in Foster Care

The 2011 GAO report, drawing on a thorough review of prescribing practices in 5 states, offers a perspective on likely trends across the county involving youth in foster care. According to Medicaid claims data from 2008, youth in foster care in each state had higher rates of psychotropic medication prescription than non-foster youth in Medicaid. Relevant GAO findings include the following:

- Youth in foster care were prescribed psychotropic medication at rates 2.7 to 4.5 times higher than non-foster youth. This was the case within each of the following age groups: 0-5 years, 6-12 years, and 13-17 years [30].
- The GAO conservatively identified three prescribing practices that carry increased levels of risk for youth and are therefore high risk practices: concomitant prescriptions of 5 or more psychotropic medications; doses exceeding maximum identified levels; and prescriptions for infants.
- The rate of youth with polypharmacy involving the prescription of 5 or more psychotropic medications concurrently was substantially greater among youth in foster care, compared to non-foster youth – approximately 10-20 times greater [30].

- Youth in foster care were found to be prescribed psychotropic medication that exceeds recommended maximum levels much more frequently than non-foster youth, despite the increased risk of side effects and absence of evidence for increased efficacy [30].
- The rate of children under age 1 who were prescribed a psychotropic medication was 2-3 higher among infants in foster care compared to infants not in foster care. Due to their age, infants are potentially more vulnerable to the effect of psychotropic medications than older children [30]. There is also an increased likelihood of psychotropic medication use among all preschoolers in foster care, not just those under 1 year of age [36].
- In a subsequent report considered later in this document, the GAO went behind review of the above three high risk practices, to determine via chart audits the extent to which a range of identified best practices in prescribing psychotropic medication were documented as having occurred [24].

The above data reflect a need to better understand and monitor prescribing practices involving youth in foster care. At the same time, the GAO points out that the higher rate of psychotropic medication use in foster care youth relative to non-foster youth “does not necessarily indicate inappropriate prescribing practices, as they could be due to foster children’s greater exposure to traumatic experiences and the unique challenges of coordinating their medication care.” Past trauma, as stated by the GAO, “creates unique treatment challenges.” Other factors contributing to the need for greater use of psychotropic medication could include the trauma of removal from home and, for some, the stress of multiple changes in foster care. It is possible that the symptoms of psychiatric disorders are more severe in youth in foster care. In addition, “In some cases, their symptoms do not clearly fit into existing diagnoses” creating additional challenges to effective treatment [30]. The larger reality is that “very little research has been done on the use of psychotropic drugs in foster children with severe symptoms.” This creates a complex clinical challenge for practitioners, where a youth’s level of need may exceed the existing knowledge base for treatment [37].

Specific Concerns Related to Psychotropic Medication Prescribing

Geographic Variability in Prescribing

One way of determining whether or not a psychotropic medication pattern is likely to be appropriate or not involves studying the degree of variation in psychotropic medication use across a specific geographic region. Leslie et al., in looking at 92 child welfare catchment areas serving 2,504 children ages 2-15 years, found a 40-fold difference in psychotropic medication use between highest and lowest utilizing communities [38]. The authors state that the data “most likely reflect both under-use and over-reliance on psychotropic medication” [38].

Increasing Use of Antipsychotic Medication

As discussed earlier, concern about SGA use applies both to youth in general and those in foster care. Data indicate an increased use of SGAs in the treatment of youth with apparent lower levels of impairment, as well as their use in combination with other psychotropic medication [33]. Given the potential for significant side effects from SGAs in general and especially in children and adolescents, another concern involves the use of SGAs for indications that are not FDA approved, where the evidence of effectiveness is limited.

Additional data related to the increased use of SGAs in youth include the following:

- From 2002 to 2007, there was a 30% increase in antipsychotic use in preschoolers ages 3-5 in foster care, based on a review of data from 47 states [39].
- During the period 2002 to 2007, overall SGA use increased in 45 states, but with a decreased trajectory of growth. After 2005, there was a decrease in use of polypharmacy, defined here as the concurrent use of 3 or more psychotropic medication classes for at least 30 days [39].
- A study of Medicaid claims data during the period, 2002 to 2007 for youth in Medicaid showed an increase of 62% in SGA use [40]. Youth with ADHD accounted for 50% of total SGA use, and 14% of these youth had ADHD as their only diagnosis. In addition, 12% of the children receiving an SGA had no mental health diagnosis at all.
- Given the above findings, the above authors recommend additional research to “broadly examine the efficacy and safety of SGA use in pediatric populations” [40].

Data indicating SGA efficacy when used to address aggressive behavior include the following:

- The Treatment of Severe Childhood Aggression (TOSCA) study [41] shows evidence of SGA efficacy in youth for aggression and oppositional behavior who also have ADHD. The study involves youth ages 6-12 years with ADHD plus severe aggression and symptoms of Oppositional Defiant Disorder and/or Conduct Disorder. The findings demonstrate the benefit of adding a SGA to a treatment protocol that combines parent training with use of stimulant medication.

Specifically, augmented therapy – involving the addition of risperidone to the parent training and the stimulant use – was found to be superior to the basic therapy (parent training and stimulant) in reducing peer aggression and ODD symptoms [41].

- More generally, a 2011 meta-analysis comparing the safety and efficacy of SGAs in patients younger than 18 years of age for indications other than schizophrenia found that the efficacy of SGAs for mania and related affective symptoms, including extreme mood variability, irritability, aggression and disruptive behavior is greater than that reported for psychotic symptoms in schizophrenia. The average number needed to treat (NNT) for mania and related mood symptoms was 2–5, compared to 3 (risperidone) – 10 (olanzapine, quetiapine and aripiprazole) for symptoms of psychosis in schizophrenia. The various SGAs show similar efficacy for non-psychotic disorders, but differ significantly in terms of safety, especially in long-term open studies related to metabolic adverse effects [42].

In each instance the cost benefit analysis of using an SGA requires attention to the side effects, including the potential for significant weight gain and other metabolic side effects.

Underutilization of Psychosocial Interventions

One of the most significant concerns about psychotropic medication use in youth involves the frequent absence of effective psychosocial interventions, including various forms of psychotherapy, along with it. In addition, the absence of psychosocial interventions can create an urgent need for intervention, often psychotropic medication, as a default response. Best practice does not involve psychotropic medication as the sole intervention for youth with complex mental health needs. Psychosocial interventions, particularly those that are evidence-based and systematically monitored, are also essential. As stated in the AACAP Practice Parameter on the Use of Psychotropic Medication in Children and Adolescents:

The prescriber who does not appreciate the need for combined psychosocial and psychopharmacological treatment for children with concomitant psychosocial problems...may unnecessarily expose the child to increasingly complex pharmacological treatment strategies [20].

Medicaid claims data and chart audits of youth in Medicaid indicate that psychotropic medication is often prescribed without concurrent psychosocial interventions:

- According to Medicaid claims data from 2005, 49% of the children in Medicaid receiving psychotropic medications that year did not receive any psychotherapeutic behavioral health services [43].
- The GAO chart audits of youth in foster care found that only 20% of youth who might have benefited from evidence-based psychosocial therapy were “mostly provided” this service. For approximately 75% of the cases, provision of evidence-based mental health treatment was only “partial” [24].

There is now an expanding array of evidence-based treatments for children and adolescents of various ages with trauma-related symptoms and for a range of mental health disorders. Evidence-based trauma treatments include the following: Trauma-Focused Cognitive Behavioral Therapy (TF-CBT website), Child-Parent Psychotherapy (CPP website), and Alternatives for Families Cognitive Behavior Therapy (AF-CBT website). Another evidence-based treatment, Parent Child Interaction Therapy (PCIT), is used to treat young children with oppositional and defiant behaviors, who are at increased risk of maltreatment or may already have experienced maltreatment [35, 44-47].

Unfortunately, these evidence-based treatments are often not available in many communities. For example, only a limited number of providers are trained in evidence-based treatments. There is a mal-distribution of mental health professionals. Evidence-based treatments may not be reimbursed or are reimbursed at unrealistically low rates. In addition, supervision may be limited, compromising treatment fidelity.

Concerns about Insufficient Engagement of Youth and Family

As valuable as evidence-based treatments may be, they are unlikely to benefit youth in the absence of youth and family engagement. As stated by the ACF, “It is essential to engage families, whether biological, foster, or adoptive, in the process of healing and recovery” [34].

Youth engagement begins with creating a welcoming environment, inquiring about the youth’s chief complaint, and soliciting information about youth strengths, interests, and future vision. The youth needs to be educated about the range of potential interventions, and have the opportunity for discussion and genuine choice. In the absence of genuine engagement, youth will feel marginalized and likely resent the involved professionals and systems. In 2008 testimony to Congress, the Deputy Director of Foster Care Alumni of America, offered insights on the need for professionals to provide empowering therapeutic relationships without immediate resort to medication:

We know that sometimes medication serves as a lifeline...We also know that medications often are given as a substitute for what young people really need – stability, love, power, hope, and someone who sees them and hears them [48].

Stenslie’s comments highlight the need for psychosocial interventions rather than medication alone, and the importance of respecting the youth’s voice and avoiding coercion:

Medication should not be the first option considered and should never be the only mode of support we receive. Pills cannot change the experiences we’ve faced or the life situations we’ve been put into....We need to know about our

own lives, and need to be the primary voice in planning and decision-making. We need...the power to seek or refuse treatment based on an educated and supported knowledge about our own lives [48].

The need for youth involvement in decision-making about the use of psychotropic medication is highlighted in AACAP's Practice Parameter for the Assessment and Management of Youth Involved With the Child Welfare System:

Involving a youth in the decision to try medication affirms the youth's role in his or her treatment and can enhance engagement in the trial and treatment in general [15].

Lack of Collaboration among Service Providers

It is important that service providers work collaboratively with one another, in responding to a youth and family. This is especially important when psychotropic medication is being used or considered. Shared information and joint planning, guided by youth and family, helps ensure that important issues are recognized and addressed, that duplication or undermining of effort is avoided, and that a biopsychosocial approach is pursued.

The use of psychotropic medication is not a process limited to only a prescriber and the particular youth. In addition to the family, all involved professionals, especially when the youth is in multiple child-serving systems, should share responsibility and have the opportunity to contribute to decision making. Once the parent or guardian has given consent and the youth given assent, it is important that all professionals support this decision.

Use of Psychotropic Medication "Off-Label":

"Off-label" refers to the use of any medication in the absence of explicit approval by the U.S. Federal Drug Administration (FDA) for a specific use. There is concern on the part of some that off-label use of psychotropic medication in children and adolescents means that such use is unsafe and inappropriate. However, the AACAP Guide for Community Child Serving Agencies on Psychotropic Medications states that it is "ethical, appropriate and consistent with general medical practice to prescribe medication off-label, when clinically indicated"[9]. Off-label prescription of medications is prevalent throughout general medical and surgical care. Moreover, there is FDA approval for psychotropic medication use for which there is no empiric evidence, such as the use of thioridazine in children as young as 3 years of age, so FDA approval does not necessarily mean that there is scientific evidence supporting safety and efficacy.

Recognition of the role of FDA approval process provides additional clarification. FDA approval involves a legally binding agreement between a pharmaceutical

company and the FDA related to the manufacture, marketing, and sale of medication. It does not address or restrict a prescriber's practice [49]. In the past, pharmaceutical companies typically did not pursue FDA approval for children for psychotropic medications that were approved for use by adults, since FDA approval for use with children would have entailed separate studies at significant expense, for a relatively small target population. However, the Best Pharmaceuticals for Children Act (BPCA), originally enacted in 2002, provided a mechanism for studying on- and off-patent drugs in children by offering an additional 6 months of patent exclusivity for on-patent drugs being tested for pediatric use. The 2013 Pediatric Research Equity Act (PREA) authorizes the FDA to require studies of drugs to ensure that the products are safe and effective for use in children. Under PREA, a pediatric assessment is required for all new medication applications, except when waived, in order to determine the safety and efficacy of the medication and to support medication's dosing and administration.

Cost-Related Concerns

Psychotropic medication use can be very expensive, due to the frequency prescribed and the cost of certain classes of medication. For example, because some of the patents still remain in effect, SGAs are very expensive, and their use is increasing. As might be expected given current prescribing patterns, youth in foster care, compared to youth on Medicaid not involved with child welfare, have higher medication costs on a yearly basis. One study of youth on Medicaid in 36 states during the years 2000-2003 found that foster care youth had twice the odds of psychotropic medication use and a corresponding \$190 higher mean annual cost for psychotropic medication, when compared to Medicaid youth not involved with child welfare [50].

Potential Misuse and Diversion of Psychotropic Medication

When a psychotropic medication is prescribed, the risk of misuse and diversion exists. Diversion of medication – selling or giving away prescribed medication – is most common with psychostimulant medications. Consumption of excessive medication at odds with the prescribed does represents another potential misuse of psychotropic medication, and this can lead to significant, life-threatening consequences. These concerns highlight the need to develop practical, feasible treatment plans, monitor progress, and cultivate positive therapeutic relationships between prescriber, youth and family [20]. Parents and other caretakers have the ultimate responsibility for the safety of medication in the home, and the treatment plan should address the need for such parental oversight [20].

Non-Adherence to Psychotropic Medication

Non-adherence to psychotropic medication treatment by the child and family may intensify the severity of the disorder, create increased need for hospitalization and

out-of-home placements, and increase the cost of medical care. If, in addition, the prescriber is unaware of the gaps in medication adherence and the child appears to be doing poorly clinically, adverse consequences may involve unnecessary increase in medication dose, discontinuation of a potentially effective medication, and/or the addition of additional, unnecessary medication. When the child resumes taking the prescribed medication, his or her safety may be jeopardized, due to medication changes made in response to the prior non-adherence.

There are many potential reasons for medication non-adherence:

- Lack of confidence by child or family in the medication prescriber.
- Unexpressed concerns about the use of psychotropic medication.
- Concern about specific side effects, especially if they are not discussed with the prescriber.
- Lack of resources to pay for the prescription.
- Limited parental oversight of the medication use.
- A youth's difficulty accepting the presence of a mental health disorder, and reluctance to accept a medication trial is really necessary.

The GAO indicates that adherence to prescribed psychotropic medication is actually higher among children in foster care than among non-foster children on Medicaid [30]. Keys to achieving medication adherence include engagement, education, shared decision-making, practical implementation, and ongoing monitoring.

Specific Side-Effects of Concern

Among the many potential side effects of psychotropic medication use in children and adolescent, four are of particular concern. These are considered below.

- *Metabolic effects of second-generation antipsychotic agents:*

There are concerns about the risk of obesity and metabolic abnormalities in children and adolescents taking second generation antipsychotic medications [51]. There is growing evidence that the association between antipsychotic medication use and diabetes mellitus is stronger in children than in adults [52]. In addition, the weight gain and other metabolic side effects associated with second-generation antipsychotics may predispose to cardiac disease over time [19]. Given the above risks, the American Diabetes Association and the American Psychiatric Association have issued a joint consensus statement recommending metabolic screening and monitoring of all patients taking second-generation antipsychotics [53].

- *Risk of Suicidality with Use of Antidepressant Medications:*

In 2004, the Food and Drug Administration issued a black box advisory warning on the potential for increased suicidal behavior in children and

adolescents taking antidepressant medications [54, 55]. While subsequent reviews demonstrated that data supporting this relationship is weak, the warning nevertheless resulted in a dramatic decrease in the diagnosis of depression in children and adolescents and an equally dramatic decline in the prescription of antidepressants in this age group [56]. Recent data indicate that the decline in antidepressant medication has been accompanied by a significant increase in youth suicidality [57]. The reasons for this association are unclear, but one possibility may be that the absence of a diagnosis and treatment diminishes the depressed youth's belief that things can get better.

- *Neurological Side Effects*

As with adults, there is significant concern about the possible onset of neurological side effects relate primarily to the use of antipsychotic medication. These may involve akathisia (extreme restlessness) and a range of extrapyramidal symptoms (EPS), the intensity of which may be related to medication dose and duration. Extrapyramidal symptoms may involve any of the following:

- Parkinsonian symptoms (tremor, rigidity, and slow movement)
- Dystonia (sustained muscular contractions involving various parts of the body)
- Tardive dyskinesia (late-onset involuntary movements, which may not be reversible).

Fortunately, the incidence of EPS including tardive dyskinesia is significantly lower with atypical antipsychotic medication (SGAs) as compared to the earlier, traditional antipsychotics, which are now used very infrequently [19].

Nevertheless, neurological side effects, including tardive dyskinesia can result from use of SGAs, and the risk of neurological side effects with the use of antipsychotic medication should be part of the discussion of risks and benefits with the child and family.

Inadequate Medical Monitoring of Prescribed Medication

Psychotropic medication use needs to be monitored for safety and effectiveness. This is especially true when there are significant side effect risks, as with second-generation antipsychotics and antidepressants. Yet data indicate that such monitoring does not routinely occur:

- With use of second-generation antipsychotics, one study found that only 30% of children on these medications had baseline glucose assessments and only 13% had lipid evaluations [58].

- The second GAO report on foster children and psychotropic medication used two child and adolescent psychiatric consultants to review foster and medical records for 24 children in foster care in five selected states [24]. The findings indicate that medication monitoring and its documentation are areas in need of improvement [24]:
 - In 54% of cases reviewed, prescriptions were “mostly monitored” by the prescriber, while in 37.5% of the cases the prescriptions were “partially monitored,” and in 8% of the cases there was no evidence of monitoring.
 - For the cases in which multiple psychotropic medications were used, only 25% cases had documentation that “mostly supported” this decision, while 70% of the cases had documentation that “partially supported” the concurrent use of multiple medications, and 5% provided no such documentation.

Key Elements of Psychotropic Medication Safety and Quality at the Clinical Level

The AACAP Practice Parameter, “Prescribing Psychotropic Medication to Children” offers useful principles to guide the use of psychotropic medication for children and adolescents and their families at the clinical level [20]. The document is divided into five sections, addressing: 1) assessment, 2) development of the treatment and monitoring plan, 3) psychoeducation and assent/consent, 4) implementation of the treatment and monitoring plan, and 5) management of complex pharmacological interventions. Taken as a whole, the document establishes the key elements of quality psychotropic medication prescribing.

Each of the following constitute key components of quality prescribing: a comprehensive psychiatric evaluation; a medical history; collaboratively-based information; a psychosocial and psychopharmacological treatment plan based on the best available evidence; a feasible medication monitoring plan with child and family; feedback and education by the prescriber to child and family; parental and youth consent, with assent by the minor child, prior to the use of medication; an adequate medication trial; reassessment based on the child’s clinical response; a clear rationale for the use of medication combinations; attention to the impact of prescribing on the youth’s self-image and self-esteem; and a specific plan for medication discontinuation.

Informed consent and assent, beyond their legal relevance, represent the implementation of collaboration and shared decision-making between the prescriber and the child and family. Although particularly important at the time of psychotropic medication initiation, informed consent and assent are ongoing processes. Informed consent involves discussion of target symptoms, likely benefits of a potential treatment, potential risks of treatment, and risks of *not* pursuing the

treatment in question. Documentation of the discussion is essential, to provide clear evidence of what occurred.

The recommended approach to beginning psychotropic medication in children and adolescents involves starting low and going slow, gradually building the dose to the optimal level based on clinical response. Medication should be used in the lowest necessary dose, with frequent monitoring of response to treatment and side-effects. Medication should also be used for as short a duration as possible, as clinically indicated. Efforts to taper and discontinue medicine may be considered when a child is asymptomatic and functioning well and continues to receive appropriate treatment and support.

Key Elements of Psychotropic Medication Safety and Quality at the Systems Level

Systems level change is mediated primarily by individual states, although the federal government has enacted child welfare legislation and provided training and technical assistance to states. The children most impacted by system level change are those on Medicaid – served by the Medicaid system either through state-sponsored managed care organizations or in fee-for-service care. Involved children may be living with their biological families or in other residential settings, including foster care for some.

While oversight and monitoring systems may be carried over to commercial insurance companies, for the most part the state lacks the jurisdiction with private insurance to mandate the same systemic changes as with children in the public sector.

The following documents, in chronological order, have helped identify key elements of psychotropic medication safety and quality at the systems level: the AACAP “Position Statement on Oversight of Psychotropic Medication Use for Children in State Custody: A Best Principles Guideline”[23]; the Tufts “Multi-State Study on Psychotropic Medication Oversight in Foster Care”[59]; and the two GAO reports from 2011 and 2014 [24, 30].

2005 “AACAP Position Statement on Oversight of Psychotropic Medication Use for Children in State Custody: A Best Principle Guideline”

AACAP, in its “Position Statement on Oversight of Psychotropic Medication Use for Children in State Custody: A Best Principles Guideline”, offers an approach to safety and quality at the systems level that consists of four comprehensive domains: 1) policies and procedures to guide psychotropic medication management, including informed consent and assent; 2) medication monitoring and oversight procedures;

3) mental health consultation; and 4) information sharing among stakeholders. These domains have been incorporated in the subsequent GAO studies on foster children and the oversight of psychotropic medication use for children [23, 24, 30].

Below is delineation of the four domains, with the specific AACAP recommendations under each of them.

A. Policies and procedures to guide psychotropic medication management, including informed consent and assent

- Identification of parties empowered to consent for psychotropic medication treatment for youth in state custody.
- Mechanism to obtain assent from minors.
- Use of family-friendly educational materials and medication information sheets to facilitate the consent process.
- Training requirements for child welfare, court personnel, and foster parents to promote their advocacy for children in CW.

B. Medication monitoring and oversight procedures

- Guidelines for the use of psychotropic medication for children in state custody.
- Advisory committee to oversee medication formulary and provide medication monitoring guidelines to prescribers of children in child welfare.
- Monitoring of the rate and types of psychotropic medication use, and the rate of adverse events for children in state custody.
- Process to review “non-standard, unusual, and/or experimental psychiatric interventions” in children in state custody.
- Data collection and analysis, with development of quarterly reports on rates and types of psychotropic medication use, made available to child welfare agencies and clinicians.
- Ongoing record of clinical information – e.g., diagnoses, height, weight, allergies, medical history, ongoing medical problem list, and log of psychotropic medications and adverse medication reactions – easily available to treating clinicians 24 hours a day.

C. Mental health consultation

- Consultation program, staffed by child and adolescent psychiatrists, which provides consultation to the person or agency responsible for consenting to psychotropic medication for the child.
- Consultation program provides consultation by child and adolescent psychiatrists to physicians/prescribers treating children in foster care.

- Consultation includes the capacity for face-to-face evaluation of youth by child and adolescent psychiatrists, when requested, in response to concerns about psychotropic medication use.

D. Information sharing laws and policies

- Relevant policies and procedures related to psychotropic medication management.
- Psychoeducational materials.
- Written consent forms.
- Adverse/side effect rating forms.
- Reports on prescription patterns.
- Links to reliable websites addressing child and adolescent mental health diagnoses and psychotropic medications.

2010 Tufts “Multi-State Study on Psychotropic Medication Oversight in Foster Care”

The Tufts study served as a catalyst for oversight at the state level of psychotropic medication use for children and adolescents. Specifically, it examined state policies and practices related to the oversight of psychotropic medication use for children ages 2 to 21 years in foster care [60]. Key state informants from 47 states and the District of Columbia, contacted between 2009 and 2010, were surveyed by phone. The states identified key challenges to medication oversight, as well as innovative state responses to some of these challenges.

The study identifies specific “red flag markers” used by states as markers of possible outlier prescribing practices. Red flags included, but were not limited to, the following: psychotropic medication use in young children, polypharmacy before monopharmacy, multiple medications simultaneously (various cutoffs), multiple medications within the same class for longer than 30 days, doses exceeding maximum recommendations, and no documentation of discussion of risk and benefits of medication. States found the use of red flags helpful at both the clinical and systems levels, through use of audits, case reviews, or data print-outs. By identifying outlier practices and prescribers, the use of red flags could prompt case reviews, lab work, use of prior authorization, and internal quality initiatives [60].

2011 GAO Report

The GAO investigators, using claims data from 2008, found higher rates of health risks (e.g., use of 5 or more concurrent medications, medication doses exceeding recommended maximum levels, and use of psychotropic medication in infants under one year of age) among youth in foster care as compared to non-foster youth in Medicaid.

The GAO also reviewed implementation by the states under study of AACAP's four identified best practice domains (2005) for the oversight of psychotropic medication use for children in state custody (2005). Each of the five states under study were found to have implemented some practices consistent with AACAP guidelines related to youth and family consent, external medication oversight, consultation programs by child and adolescent psychiatrists, and information-sharing processes. However, progress in these areas was variable, with opportunity for improvement by each of the states in each area [30].

2014 GAO Report

This report tracks progress made by states and the federal government related to the monitoring and oversight of psychotropic medication for children in foster care since the release of its 2011 report. The two key components involve the following:

- Determination of the quality of clinical practice through chart reviews by two contracted child and adolescent psychiatrists. This involved review of randomly selected cases from the five participating states, to determine the frequency of appropriate prescribing practices, as demonstrated in chart documentation.

Reviewers found documentation that only partially supported the identified best practices – pediatric medical examinations, psychiatric evaluations use of evidence-based therapies, treatment to address the impact of trauma, appropriate monitoring of prescriptions, appropriate medication dosages, justification for concurrent use of multiple medications, informed consent, communication between treatment providers, and review of psychotropic prescriptions to infants. Variability was found from state to state and from category to category, and there was room for improvement.

- Determination of the frequency of statewide policies and procedures that address psychotropic medication oversight.

A key mechanism for medication oversight, as found in the states under review, involves the use of “red flags” as a trigger for a medication review. Another tool involves use of prior authorization. A key need involves collaboration among systems. Variability was found from state to state, with need for additional state implementation of oversight procedures [24].

Discussion

Use of psychotropic medication for children and adolescents needs to be considered within the broader context of quality mental health treatment. Youth with

psychiatric disorders, especially trauma and other complex mental health disorders, need to be evaluated and treated in a holistic way that provides comprehensive understanding and guides comprehensive treatment. This is achieved through use of a biopsychosocial framework and the implementation of trauma-informed and system of care-based principles.

When indicated, psychotropic medication should be prescribed at the clinical level according to existing standards of practice identified by AACAP [20] (2009), and its use should also be monitored and subject to oversight at the systems level. Except in the most uncomplicated situations, psychotropic medication should not be a stand-alone intervention. It should be provided in conjunction with evidence-based psychosocial interventions implemented with fidelity. Especially for youth with a history of trauma, “any effort to ensure the appropriate use of psychotropic medication...must be accompanied by increased availability of evidence-based psychosocial treatments that meet (their) complex needs” [29].

The need for states and communities to have a clearly delineated process for medication monitoring and oversight is highlighted by the following findings discussed earlier:

- The increased use of psychotropic medication in foster care compared to other youth in Medicaid.
- Widely divergent variations in prescribing practices within a given geographic area.
- Increased rates of use of SGAs alone and in combination with other medication classes in less impaired youth, including SGA use in some youth with only ADHD and in others with no mental health diagnosis at all.

At the same time, it is appropriate to also bear in mind the following:

- The research base on treating mental health disorders, while growing, remains limited. As stated by Olfson, “One of the cross-cutting findings to emerge from the large federally funded clinical treatment trials of the common childhood psychiatric disorders...is that many children do not achieve remission from available pharmacological or psychological monotherapies [31]. As a result, “physicians commonly (must) venture into therapeutic territory that is uncharted by clinical research” [31].
- Although the evidence-base may currently be limited, there is research that supports the careful and judicious use of some medication combinations, such as SGA use along with parent training and psychostimulant use for ADHD and severe aggression in the TOSCA study [41], the addition of guanfacine to psychostimulant medication in the treatment of ADHD [59], and the need for a mood stabilizer when antidepressant medication is used for bipolar disorder [61].

- The absence of an evidence-base *in favor of* a specific practice should be distinguished from evidence of *ineffectiveness* of that practice. It is possible that additional research may validate some of the practices currently lacking evidence, at least in some qualified situations.
- Thus, at the same time there is need for medication monitoring and oversight, given the unmet needs of many youth with complex psychiatric presentations there is also a clear need for additional research into the effectiveness of various psychosocial and psychotropic interventions.

Finally, the involvement of two child and adolescent psychiatrists in the 2011 and 2014 GAO studies illustrates how child and adolescent psychiatrists can provide expertise and leadership in the effort to improve the use of psychotropic medication for children and adolescents at both the clinical and systemic levels [24, 30].

Recommendations

Recommendations fall into three general categories: clinical practice, psychotropic medication monitoring and oversight, and research

Clinical Practice

1. Prescribers of psychotropic medication for children and adolescents, and others working with them and their families should adhere to a developmentally-informed biopsychosocial approach, trauma-informed care principles, and system of care principles.

Everyone involved with the child and family needs a common foundation for holistic, ethical, effective care. The biopsychosocial approach ensures that the strengths and needs of the child in all contexts are understood and addressed. Trauma-informed principles highlight the significance of trauma and promote ethical, empowering relationships between providers and children and their families. System of care principles provide additional ethical guidelines for care and help maximize existing resources while promoting prevention, early intervention, and intensive treatment.

2. When psychotropic medication is being considered, children and adolescents should receive a comprehensive behavioral health assessment.

The needs of children cannot be satisfactorily addressed without basic information about their psychosocial context, behavioral health status, and level of functioning.

A comprehensive behavioral health assessment can also provide information about the child's trauma history and safety. Results of the assessment can guide additional interventions.

3. Prescribers of psychotropic medication should actively engage and collaborate with children and adolescents and their families when they are referred for potential use of such medication.

Engagement of children and adolescents and their families is a prerequisite to effective mental health treatment, including the use of psychotropic medication.

Creating a genuine therapeutic alliance and demonstrating a readiness to listen

and incorporate the child's "voice" into treatment planning are core components of the medical role.

4. Prescribers should actively engage and collaborate with other professionals and systems involved with the child and family.

Quality care requires collaboration among all involved professionals, with exchange of information, understanding of differing roles and responsibilities, and a commitment to team-based decision-making.

5. All youth with complex behavioral needs, including youth in foster care, should receive a combination of evidence-based psychosocial interventions and psychotropic medication when indicated, not just psychotropic medication alone.

For children with complex needs, positive outcomes are best achieved through the use of effective psychosocial interventions in combination with psychotropic medication. It is unrealistic to expect that psychotropic medication alone will be effective.

6. Clinical guidelines identified in the AACAP Practice Parameter, "Prescribing Psychotropic Medication to Children" [20] should be implemented.

The above document identifies the core components of quality prescribing, including psychoeducation for child and family, informed consent and assent, systematic monitoring of side effects and clinical progress over time, and collaboration with child and family on an ongoing basis.

7. Prescribers should promote awareness of potential adverse effects and carefully monitor for such side effects over time.

Such monitoring is especially important with the use of SGAs and mood stabilizers. Consistent with the AACAP Practice Parameter for the use of atypical antipsychotic medications for children and adolescents, important variables include weight, blood pressure, blood glucose and lipid profile, and evidence of neurological side effects [19].

Psychotropic Medication Monitoring and Oversight

8. Non-physician professionals working with youth should have knowledge of the guidelines in AACAP publications and other relevant resource documents relevant to the use of psychotropic medication with youth.

Relevant documents may vary for professionals according to the system they are in and their specific role. Service systems and agencies can determine the documents needed for basic orientation and subsequent training.

9. Mental health agencies, child welfare, Medicaid agencies, and managed care organizations should collaborate to create systems to monitor, review, and inform practice patterns with psychotropic medications.

Important infrastructure elements include common data systems or at a minimum the capacity to share data; common practice expectations; common monitoring standards; methods for data review; identification of red flag criteria triggering external reviews; criteria for prior authorization; and methods for timely feedback to prescribers.

10. States and county agencies serving children in foster care should use the Best Principle Guideline in the 2005 AACAP Position Statement as the framework for developing formal monitoring and oversight programs [23].

The AACAP Best Practice Guideline identifies four core components for monitoring and oversight infrastructure:

- Development, in consultation with child and adolescent psychiatrists, of “policies and procedures to guide the psychotropic medication management of youth in state custody [23].”
- Development, in consultation with child and adolescent psychiatrists, of “effective oversight procedures [23].”
- Development of “a consultation program administered by child and adolescent psychiatrists [23].”
- Development of a website “to create ready access for clinicians, foster parents, and other caregivers” to relevant policies and procedures, specific forms, educational information, data, and links [23].

11. Consultation programs should involve child and adolescents psychiatrists, who can offer technical assistance, second opinions, and case review when indicated.

Given the increase in psychotropic prescribing for children and adolescents by primary care physicians, a voluntary consultation program could provide meaningful technical assistance and support to the non-psychiatric physician in the medical home. The availability of a voluntary “second opinion” can also be helpful for psychiatric prescribers.

Consultations can also be made available to a state or county agency. Based on the design of the program, the consultation can involve chart review, telephone conversation, and face-to-face assessment by the child and adolescent consultant,

Mandatory consultations with an identified child and adolescent reviewer can be an effective mechanism for an oversight body, in response to identified red flags.

12. Monitoring methods should entail a combination of approaches that includes review of aggregate data on prescribing patterns, chart audits, and tracking of specific red flag markers.

Because it is the ultimate responsibility of the prescriber to exercise best judgment when prescribing a specific medication, chart audits can be especially helpful in determining the extent to which best practice prescribing standards for psychotropic prescribing have been followed and documented.

13. Child and adolescent psychiatrists should participate in the development of monitoring and oversight standards in their state and community, and involved systems should actively support their involvement...

Active involvement by child and adolescent psychiatrists in system redesign increases the level of expertise in the development of monitoring and oversight decisions, and also helps to engage them positively in the process.

14. Psychotropic medication monitoring and oversight efforts should involve ongoing collaboration among state and county agencies as well as managed care organizations.

All of the involved agencies and organizations need to work together. Collaboration involves agreed-upon standards, clear delineation of roles, information-sharing, and a commitment place the needs of the youth first.

15. Systemic oversight of psychotropic medication prescribing should be pursued in a collegial manner that promotes the use of evidence-informed practice.

This involves actively disseminating information about practice standards and oversight practices, providing physician training, and ensuring the availability of consultation by designated child and adolescent psychiatrists as requested and as needed.

16. Systems for medication review and for the approval or denial of psychotropic medication requests should be streamlined and efficient, to avoid unnecessary treatment delay or provider burden.

At the same time that quality standards are established and implemented, children and adolescents need to get “the pharmacological treatment they need in a timely manner” [23]. When prior authorization is required, timely responses to medication requests need to be ensured.

17. All stakeholders and child-serving systems responsible for youth with complex mental health needs should advocate for increased availability of evidence-based psychosocial interventions by qualified staff.

Youth with severe trauma or other complex behavioral health needs should have access to effective psychosocial interventions, not just psychotropic medication. Use of psychotropic medication should be accompanied by use of evidence-based treatment and not a result of the absence of available services.

Research

18. Clinical research is necessary to investigate the most effective approaches to prevention, early intervention, and treatment of complex behavioral health needs of children and adolescents.

Such research can have many areas of focus, including the following:

- Comparing the relative benefits of psychosocial interventions, psychotropic medication, and the combined use of psychosocial interventions and psychotropic medication.
- Comparing different classes of medication in the treatment of specific disorders, and the differential effects of medications within the same class.
- Comparing the effects of lower vs. higher doses of medication in the treatment of specific disorders.
- Prospective, randomized, controlled research comparing treatment outcomes for youth with PTSD and complex trauma, aggression, and a range of comorbid conditions, using psychotropic monotherapy vs. targeted medication combinations.

IX. Conclusion

Psychotropic medication has a legitimate, established role in the treatment of children and adolescents with mental health disorders. Its use should be guided by a biopsychosocial perspective and by core values embodied in trauma-informed care and system of care principles. Of particular importance is the need for prescribers and other professionals to act within a framework that is individualized, family-driven, and youth-guided, with recognition that collaborating with children and families is both an ethical and a pragmatic imperative. The presence of a

positive therapeutic relationship is itself therapeutic [62], and such relationship with the prescriber will be likely to improve the child's ultimate response to medication, when used.

At the clinical level, the use of psychotropic medication is a significant medical event and should not be an isolated activity. In the vast majority of cases, psychotropic medication should not be used by itself without concurrent, effective psychosocial interventions. When access to effective psychosocial interventions is limited, it is the responsibility of all of those involved in the care of youth with psychiatric disorders to advocate for increased access, including increased training of a workforce that can provide these therapies.

As identified by AACAP and used by the GAO in its reports, best practice standards exist for the appropriate prescribing of psychotropic medication for youth. In developing monitoring and oversight processes, each state must build its own system, engaging a range of stakeholders and drawing upon the expertise and experience of child and adolescent psychiatrists.

Finally, additional research is needed to assess the safety and efficacy of psychotropic medications for the treatment of various childhood psychiatric disorders. Research should include comparative studies between medications, psychosocial interventions, combined psychosocial interventions and medications, and placebo. Studies comparing the effectiveness of different medication classes and different medications within a class would further guidance on medication choice. Research is also needed on the safe and effective use of psychotropic medications in complex co-morbid disorders, especially those co-morbid with complex trauma and aggression.

AACAP is committed to promoting prescribing practices that are safe and of high quality, and oversight and monitoring practices based on best practices that promote collaboration among systems and professionals. Child and adolescent psychiatrists can offer support, leadership and expertise to these important efforts.

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