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A Knowledge Agenda for Studying Psychotropic Medication in the Child Welfare System: Technical Report, Florida Institute for Child Welfare

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TECHNICAL REPORT

A Knowledge Agenda for Studying Psychotropic Medication in the Florida Child Welfare System

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FLORIDA INSTITUTE
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Executive Summary

Many questions persist regarding the use of psychotropic medication in Florida's child welfare system. The purpose of this report is to (1) describe both the broad and local contexts (including research and policy) for the use of psychotropics in child welfare, and (2) to propose a research agenda which could realistically lead to improvements in the Florida system. This technical report provides an overview of the issues that are most relevant and pressing for the Florida child welfare system. The report also presents a set of recommendations that can improve the knowledge base through the development and implementation of empirical research that can produce relevant and valid findings for future practice and policy.

The prescription of psychotropic drugs to children in the child welfare system has rightfully attracted increasing attention over the past decade. Over this same time period, the profession of psychiatry has experienced a series of important debates, critiques and controversies about the use of psychotropic medication with adults and children. These have taken place at both the scientific and practice levels. This is important to note because practices in the Florida child welfare cannot help but be impacted to a large extent by "upstream" dynamics. Significant problems include (1) the integrity of the scientific literature that concerns the use of psychotropic drugs; (2) the nature and scope of the influence of pharmaceutical companies on prescribing patterns; (3) the regulatory rigor of the U.S. Food and Drug Administration; (4) the accuracy of psychiatric diagnosis that provides the basis for prescribing decisions; and (5) the efficacy of psychotropic drugs and their long-term impacts on children. The disconnect between the scientific data and conventional wisdom is likely to be large and represents a major barrier to evidence-based prescribing and decision-making. In such a vulnerable population, such issues should raise deep concerns.

The relative lack of influence of the emergent scientific data on conventional psychiatric medication practices is significant and represents major barriers to evidence-based prescribing and decision-making. The long-term effects of psychotropic medication during childhood are only beginning to be understood, but most researchers agree that these are non-trivial for the children involved. In light of this situation, the special vulnerabilities of the child welfare population as a subset of all children using such medications should raise deep concerns and inspire an abundance of caution.

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The State of Florida has developed a well-considered set of policies and procedures regarding the use of psychotropic medications with child welfare clients. These include pre-authorization for reimbursement, available consultation, and medication reports that are posted publicly on the Internet on a weekly basis. Since June of 2013, Florida has experienced a sustained if modest decrease in the use of psychotropic medication in the child welfare population. The number of medicated children in 2016 ranged from 2,491-2,636. The average proportion of medicated children in 2016 stood at 11.2 percent. Broken down by age, this represents 1.2 percent of 0-5 year-olds, 17.8 percent of 6-12 year olds, and 26.9 percent of 13-17 year-olds.¹ There are sharp differences in the rate of medication depending on placement setting. Children in licensed substitute care receive medication at much higher rates than those placed in relative/non-relative care (i.e., for ages 0-5, 2.0 percent vs. 0.7 percent; for ages 6-12, 27.6 percent vs. 10.3 percent; for ages 13-17, 36.1 percent vs. 11.3 percent). Over the past few years, consent for medication has been obtained in ~99 percent of cases documented in the FSFN database.²

The following five recommendations are proposed for consideration:

- 1) *Systematically and rigorously measure the degree to which current policies are well-implemented throughout the Florida system.* Based on these study results, fine-tune the implementation of Florida's existing policies and procedures regarding psychotropic drugs.
- 2) *Strengthen the role of trauma-informed psychosocial services in the child welfare system and evaluate the service outcomes.* Optimally, service outcomes should be evaluated through assessing the risk:benefit ratios to children in the child welfare system. Cost-benefit analysis and other outcome studies could help assess whether an emphasis on trauma-informed, psychosocial strategies with child welfare clients prove to be more or less costly in the long-term as compared to more psychotropic medication use and other treatment-as-usual.
- 3) *Future studies in Florida should collect additional data on how frequently psychotropic medication withdrawal is attempted.* Existing scientific outcome studies of the use of psychotropic medication show that it is primarily associated with short-term benefits; longitudinal data showing effectiveness are rare. Research should be designed to evaluate the range of opportunities for medication withdrawal. Among children in stable placements, it will be important to compare outcomes among children that are slowly and conservatively withdrawn from psychotropic medication with those children who remain on medication.
- 4) *The effectiveness of informed consent and approval processes should also be studied.* At the least, this will involve careful and reiterative reviews of the informational materials used in the process of informing patients, prescribing or judicial decision-making. Ensure that such materials reflect the most current scientific data on the potentials risks and benefits of psychotropic medication to children.
- 5) *Enhanced tracking and reporting of data regarding psychotropic medication may be beneficial.* At present, the publically available FSFN data aggregates all children as "medicated" or "not", a low-resolution look at the issue (e.g., a sleeping medication and antipsychotic are counted as equivalent). A more refined form of data reporting could be useful. Additionally, the number of children who enter the child welfare system on medication is another potentially useful metric.
- 6) *Implement training for service providers on the topic of psychotropic medications, and scientifically evaluate the training and practice outcomes.* Training can only improve child welfare outcomes if it can be demonstrated, first, that practitioners actually adopt the new approaches and then apply them with fidelity; and, second, that child outcomes are positively enhanced by these modified practices.

What is Currently Known

The use of psychotropic medications in the child welfare system is an important issue that has attracted increasing levels of attention in recent years. Many children in the child welfare system suffer from mental health problems³ and a subset is prescribed psychotropic medications. Psychotropic medications are seen as an integral part of psychiatric/medical treatment and are clearly linked to Child and Family Service (CSFR) outcomes: 1) Children receive appropriate services to meet their physical and mental health needs and 2) Children receive appropriate services to meet their educational needs.

Psychotropic medications refer to prescription medications used to alter a person's mood, cognition, and/or behavior. These drugs are generally classified as antidepressants (e.g., Prozac), antipsychotics (e.g., Risperdal, Seroquel), stimulant and non-stimulant drugs prescribed for Attention-Deficit Hyperactivity Disorder (ADHD) (e.g., Adderall, Strattera), anxiolytics or anti-anxiety drugs (which include some antidepressants and also drugs such as benzodiazepines [e.g., Klonopin, Xanax], anticonvulsants (e.g., Depakote, lithium), or hypnotics [e.g., Ambien, Lunesta]).⁴

The use of psychotropic medication in the Florida child welfare system has been the subject of previous examination, with reports issued in 2003 and 2009.^{5,6} While some progress has been made, psychotropic treatment in the child welfare system remains a controversial issue, especially since the General Accountability Office expressed concerns about the medicating of foster children.⁷

Over this same time period, the profession of psychiatry has gone through a series of important debates, critiques and controversies—both at the academic and practice levels.^{8,9,10} This is important because child welfare practices in Florida cannot help but be impacted to a large extent by the existing issues “upstream” which often go unmentioned in the child welfare literature, but are likely to play out in the psychotropic treatment of children. In this report, we include several disconnected literatures in order to paint the most useful picture of the current dilemmas surrounding psychotropic medication of children.

The Broader Context for Psychotropic Medication in Child Welfare

Evidence-based Medicine

Since the late 1990s, medicine has embraced the formal paradigm of Evidence-based Medicine¹¹ (EBM), which argues that clinical decisions should be made according to best evidence available – while also including client preferences and clinical judgment in decision making. EBM relies heavily on data from rigorous studies on diagnosis and treatment, such as placebo-controlled clinical trials of psychotropic medication. Evidence-based Practice (EBP),¹² used in studying psychosocial interventions, is largely derived from EBM. In both EBM and EBP, rigorous tests of hypotheses trump anecdote or authority; important questions are ostensibly settled by data.

Pharmaceutical Company Influence

It is impossible to discuss psychotropic medication without mentioning the massive influence of the pharmaceutical industry. Global pharmaceutical sales reached nearly 1 trillion dollars in 2012¹³ and many of the “blockbuster” drugs (>\$1 billion in sales) over the last decade have been psychotropic medications. Drug companies influence the public through direct-to-consumer advertising,¹⁴ funding of advocacy groups and “disease awareness” campaigns. The industry is very adept at influencing prescribers through pharmaceutical representatives and other means.¹⁵ Multi-billion dollar settlements for illegal activity such as off-label marketing (promoting a drug for a purpose it is not approved for, such as use in children) have become routine,¹⁶ especially among manufacturers of psychotropic drugs.¹⁷

Pharmaceutical companies have long marketed their products directly to physicians (and to consumers) since 1997, but over the past 25 years, they have leveraged their influence on the scientific and clinical literature. Given the promise of EBM, it may be seen as ironic that observers have catalogued a host of problems with the modern research literature in psychiatry, many of which are inadvertently facilitated by medicine’s commitment to the EBM model.¹⁸ This was accomplished through corporate ghostwriting of journal articles;^{19,20,21} selective reporting of data²² (publishing positive studies or presenting negative findings as positive); duplicate publication of data;²³ and coding study data in order to downplay adverse effects.²⁴

Emblematic of these problems, Study 329, a randomized controlled trial of the antidepressant Paxil for children and adolescents, was published in the *Journal of the Academy of Child and Adolescent Psychiatry* in 2001.²⁵ The publication was co-authored by some of the most influential child psychiatrists in the field. It concluded that Paxil was “generally well tolerated and effective for major depression in adolescents,” reporting that the only adverse effect caused by Paxil²⁶ was a headache suffered by one patient.^{27,28} GlaxoSmithKline (GSK) promoted Paxil as having “REMARKABLE Efficacy and Safety,”²⁹ and the study was cited positively throughout the scientific literature.³⁰ For prescribers who were reluctant to write antidepressants to children, the results were likely reassuring.

Multiple lawsuits filed against GlaxoSmithKline^{31,32} eventually led to the public disclosure of internal documents and the study data. It came to light that GSK was well aware that Study 329 found Paxil ineffective with a significant number of adverse effects, but paid a ghostwriter to shape a manuscript that would still allow them to market Paxil. The prestigious medical journal *Lancet* characterized the story of Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants in children as “one of confusion, manipulation, and institutional failure”³³ When a re-analysis of the original Study 329 data was finally published in 2015, it found that Paxil was no more effective than placebo, and that there was more suicidal and self-injurious behavior among the children prescribed Paxil.³⁴ Despite the new results, the journal has not retracted the original study.³⁵ Importantly, the story behind Study 329 became well known because of litigation, not the scientific process. Perhaps strangely in an era of evidence-based medicine, reading the peer-reviewed literature without consulting documents from litigation could result in being misinformed^{36,37,38,39}.

It can be argued that this bias flows from research to practice, towards over-diagnosis, overtreatment, and overestimation of the efficacy of psychiatric drugs.⁴⁰ When one also considers the generous funding of influential academic psychiatrists by pharmaceutical companies⁴¹ who popularize both diagnoses and treatments,⁴² concerns about bias and distortion seem warranted. Well-intended prescribers endeavoring to base their clinical decisions on the best available evidence may therefore be misinformed by the very literature valued by EBM.

Diagnostic Reliability

An accurate diagnosis is an important first step in the EBM model. Treatment guidelines, FDA approval, and other important issues are organized by diagnostic categories. Ostensibly, having the correct diagnosis facilitates treatment planning and allows the prescriber to select the correct treatment (i.e., the appropriate medication). Also, symptoms can be viewed through a diagnostic lens; similar behaviors can be seen differently depending on the child’s diagnosis. Accuracy of psychiatric diagnosis has historically been

measured through inter-rater agreement⁴³ or test-retest agreement. These measure how often two clinicians who see the same client independently arrive at the same diagnosis. The rationale for the modern DSM^{44,45} system of symptom checklists is to ensure good reliability. The lack of any laboratory tests and the constant use of clinical judgment in interpreting a child's behavior makes this a crucial issue, especially for children in the child welfare system.

The DSM-5 was published in 2013, and the American Psychiatric Association conducted field trials assessing the reliability of psychiatric diagnoses.^{46,47} The field trials took place at prestigious psychiatric research centers, with well-trained clinicians using standardized instruments and diagnosing patients who had been pre-selected because they were already diagnosed with the mental disorder being tested.⁴⁸ The childhood disorders trial results for this important study are summarized in Appendix A. There was 69 percent agreement for Autism and 61 percent for Attention Deficit Hyperactivity Disorder (ADHD); for ADHD, these are similar results to those published in the 1980 DSM-III.⁴⁹ Other childhood mental disorders had much lower agreement: for instance, Major Depressive Disorder and Disruptive Mood Dysregulation Disorder were under 30 percent. The field trials were unable to estimate the reliability of several childhood disorders, such as Bipolar Disorder (see Appendix A). Overall, it can be assumed that the reliability numbers found in the field trials are higher than would be found in routine clinical practice.⁵⁰

Given the relationship between diagnosis and prescription of psychotropic drugs, the ramifications of diagnostic inaccuracy are important to consider. Some have argued that the DSM diagnostic criteria (for instance, for ADHD) are more likely to result in false-positive than false-negative results.⁵¹ That is, application of the flawed DSM to troubled children will result in some proportion of children receiving a diagnosis who do not technically qualify for the mental disorder they are diagnosed with. There is lack of data on this issue, but the potential consequences of poor reliability become even more important when prescription of psychiatric medication follows a diagnosis. While the low reliability of some common childhood diagnostic categories is not an issue that can easily be solved, it is a commonly overlooked issue when considering clinical practices that rely on diagnosis⁵² and treat it as accurate—especially given the confounding high rates of trauma and neglect in the child welfare population.

Current Understanding of Mental Disorder and Medication

The brain is the most complex organ in the body, and scientists have no clear understanding of “normal” cognition and behavior.⁵³ While neuroscientists continue to generate research that improves our understanding of the brain, the complexity of the brain has thus far defied explanation, and it has been said that we are in the “very beginning” of brain science.⁵⁴ This partially explains why scientists have thus far been unable to identify clear biological causes (pathophysiology) for mental disorders. The profession of psychiatry has been persistently optimistic about the integration of neuroscience and psychiatry,⁵⁵ but these efforts have failed so far. At present, there are no brain scans, blood tests, or biological tests for mental disorders.^{56,57} Mental disorders are currently thought of as biopsychosocial in nature. This conventionally means they result from the interaction between biological, psychological, and social factors. While they are often assumed to be biological, causal faulty biology cannot yet be identified and non-medical treatments are often successful.

Unfortunately there is a large disconnect between the understandings of mental health researchers and the general public regarding the cause of mental disorder, and complex issues are often oversimplified—or the public is under the impression that the science is more settled than it actually is. As just one example, pharmaceutical companies marketed the idea of a “serotonin imbalance” underlying depression, and although this hypothesis was falsified long ago, chemical imbalance was soon part of pop culture, and was even used in some clinical interactions between prescribers and patients.⁵⁸ Surveys repeatedly find that the majority of respondents believe that a chemical imbalance underlies depression.⁵⁹ Such respondents have seemingly absorbed a pharmaceutical company marketing tactic as a scientific fact.⁶⁰ This suggests major difficulties in the dissemination of accurate information to the public, primary care physicians, and mental health patients, especially so as the antiquated chemical imbalance theory may encourage a prescription for psychotropic medication.

Metaphorical explanations are also often used for the action of medications, e.g., statements are used such as “antidepressants correct a chemical imbalance in the brain” or “psychiatric medications are like insulin for diabetes.” Such statements cannot be justified with scientific evidence. Current scientific thinking is more complex, which may explain why metaphorical explanations are sometimes used. Chronic administration of psychotropic drugs perturbs brain function; as the brain reacts, this produces an “adapted state” which “may be qualitatively as well as quantitatively different from the normal state.”⁶¹ Given the complexity of the brain and our poor understanding of it, the brain changes generated by psychotropic drugs are not well-understood,^{62,63} particularly in the developing brain of a child.

FDA Approved Medications

In the United States, prescription-only medications are approved by the Food and Drug Administration (FDA) for specific indications.⁶⁴ Any use outside of these indications is considered “off-label”, meaning the indication is not approved by FDA for children. FDA approval is more ideal than not—indicating the medication has passed through a process of safety screening and monitoring. Importantly though, FDA approval does not mean that a medication has been found to be highly effective on a clinically significant basis. In fact, FDA approval does not mean that a medication helps a psychiatric condition to remit or that it works better than existing drugs or psychosocial treatment. Drug companies need only submit two positive trials to the FDA to get approval, no matter how many negative trials have taken place, and many psychotropic drugs have been approved when the overall body of data is that of failed studies, or studies showing questionable clinical efficacy.^{65,66}

FDA approval does not mean that a medication has been found to be highly effective on a clinically significant basis.

Adverse Effects

When new psychotropic drugs are first introduced into the marketplace, they follow a somewhat predictable cycle (“the 10-20-30 year cycle”),⁶⁷ so named because it may take decades to get an accurate picture of a psychotropic medication. At first, spurred by initial optimism, they are introduced as near-panaceas, and adverse effects are not reported or downplayed. Subsequently, there ensues more and more skepticism regarding the efficacy of the drug and the nature of adverse effects.⁶⁸ Once the drug goes generic and promotional efforts cease, it is common for a more realistic appraisal of a drug to follow.

When considering prescription to children and adolescents, especially newly introduced medications, it is important to acknowledge that the risk-to-benefit ratio is not clearly known for some time. For example, SSRIs were first reported to cause sexual dysfunction at a rate of 1.9 percent,⁶⁹ which was eventually revised up to 70 percent for some particular medications.⁷⁰ Case reports of SSRI-induced suicidality⁷¹ emerged shortly after Prozac was released, but it was decades before FDA issued a black box warning. Also, some effects of medication may not be obvious or be acknowledged on the product label. For instance, atypical antipsychotics are now well-documented to cause negative metabolic, neurological, and cardiological effects.⁷² However, a long-term study suggests that antipsychotics are associated with subtle atrophy (shrinkage) of the brain.^{73,74}

Adverse behavioral effects of psychotropic medication are also of concern. Children prescribed antidepressants can become ‘overly activated’, manic, or hypomanic at higher rates than children prescribed placebos.⁷⁵ These adverse effects, and others, can be mistaken for psychiatric symptoms and trigger a “prescribing cascade” whereby additional medications are prescribed to deal with the new medication-induced problem.

Efficacy

A recent editorial in JAMA Psychiatry recommends that clinicians exhaust low-risk psychosocial treatment options for children not diagnosed with a psychotic disorder before prescribing antipsychotics.⁷⁶ This was published in response to an article demonstrating that antipsychotics were being prescribed for non-psychotic problems such as aggressive and impulsive behaviors, as well as ADHD.⁷⁷ Disturbingly, outpatient psychotherapy behavioral health insurance claims were uncommon (less than 25 percent) among those prescribed antipsychotics.⁷⁸

Children are often prescribed psychotropic drugs for long periods of time, so long-term data are preferable whenever possible, yet are rare in the literature. There are a great number of short-term studies of psychostimulants such as Ritalin (methylphenidate), showing that they reduce hyperactivity and increase focus. In the 1990s, the National Institute of Mental Health (NIMH) funded the Multimodal Treatment of ADHD (MTA) study comparing psychosocial and medication treatment over many years.⁷⁹ The initial study report concluded “that for ADHD symptoms, our carefully crafted medication management was superior to behavioral treatment and to routine community care that included medication. Our combined treatment did not yield significantly greater benefits than medication management for core ADHD symptoms, but may have provided more advantages for non-ADHD symptoms and positive functioning outcomes”.⁸⁰ However, at the three-year mark, medication was “a significant marker not of beneficial outcome, but of deterioration,” with medicated children showing increased levels of symptoms compared to those not on medications.⁸¹ At year six, medicated children were more functionally impaired and had “worse hyperactivity-impulsivity and oppositional defiant disorder symptoms.”⁸² While methodological issues⁸³ complicate the interpretation of this study, by year eight, the authors had concluded, “these long-term follow-up data fail to provide support for long-term advantage of medication treatment beyond two years for the majority of children.” Thus, the finding of short-term efficacy must be balanced with these longer-term findings.

The disconnect between research findings and conventional wisdom is also apparent in two large-scale reviews of the psychostimulant literature for ADHD published in the last decade. In 2006, a review of 2,287 stimulant studies from Oregon Health and Science University found that “Good-quality evidence on the use of the drugs to affect outcomes relating to global academic performance, consequences of risky behaviors, social achievements, etc., is lacking.”⁸⁴ A just-published review of Ritalin from the prestigious Cochrane Collaboration reached very similar conclusions.⁸⁵

The federally-funded Treatment for Adolescents with Depression Study (TADS) study compared inactive placebo (a “sugar pill”), Prozac, Cognitive-Behavioral Therapy (CBT), and Prozac + CBT in the treatment of depressed adolescents.⁸⁶ Medication groups had faster results (in terms of ratings on scales); for instance, at 12 weeks, 43 percent of the CBT group were recovered versus 61 percent of those on Prozac. TADS is commonly cited as supporting the use of combination treatment,⁸⁷ as 71 percent of the children randomized to Prozac + CBT recovered at 12 weeks. But deciding whether to prescribe medication is a complicated decision weighing risk versus benefit; psychiatric adverse effects (including mania and agitation) were experienced by 18 percent of those on Prozac alone, and by 11 percent of those on combination treatment, but only by 1 percent receiving CBT.⁸⁸ At 18-month follow-up, 81 percent of the CBT group had recovered, the same rate as Prozac alone.⁸⁹ There was a five percent advantage for combination treatment (86 percent recovery rate) over CBT.⁹⁰ Thus, the decision to prescribe antidepressants to depressed children is a complex clinical decision that must weigh potential risk versus benefit while considering both the short-term and long-term data. Part of the context for such clinical decisions is the low reliability of the depression diagnosis (28 percent agreement between clinicians).⁹¹

There are other types of research designs that should be considered when evaluating psychotropic medication, such as naturalistic studies in the community. One such study found positive effects associated with medication, but even while the medicated children continued to manifest symptomology in the clinical range.⁹² Qualitative studies have been published where children report their experience of medication, including positive experiences.⁹³

Trends in Psychotropic Prescriptions to Youth

While the use of psychotropic medications as first-line treatments for youth with emotional and behavioral problems was relatively low as recently as the 1980s, prescriptions to children and adolescents have risen markedly since then.^{94,95,96} Historically, it was estimated from a nationally representative sample of the general youth population that psychotropic drug use increased from 1.4 percent of children in 1987 to approximately 4 percent in 1996.⁹⁷ This included a 400 percent increase in the prescription of stimulant drugs.⁹⁸ By 2002, an estimated one out of every 40 children in the United States was prescribed an antidepressant drug.⁹⁹ As of 2011-12, a federal government survey found that 7.5 percent of children aged 6-17 were prescribed psychotropic medication.¹⁰⁰ A consistent finding is that children on Medicaid and/or living in poverty receive such medications at a higher rate than non-Medicaid children. In 2011, 9.9 percent of Medicaid/CHIP children received medication as compared to 6.7 percent of children with private insurance.¹⁰¹

In general, the prescription of antipsychotics to children and adolescents has risen substantially in the past 15 years. From 1997 to 2006, the prevalence of antipsychotic prescriptions rose from 1.2 percent to 3.2 percent among Medicaid-enrolled youth.¹⁰² There are many suggested explanations for this rise which are relevant to child welfare, including: 1) an attitude of acceptability regarding psychotropic treatment of youth in the United States as compared to some other countries;¹⁰³ 2) the perceived clinical efficacy of antipsychotics for behaviors such as aggression in autism; 3) a lack of access to non-medication (psychosocial) interventions; 4) a desire for rapid clinical improvement; and 5) mental health screening and treatment which takes place in primary care settings.¹⁰⁴ Data on some of these proposed explanations are not readily available. However, an analysis of pediatric prescribing patterns within Florida Medicaid found that roughly a quarter of both antipsychotic and antidepressant prescriptions, and over half of stimulants, were written by primary care physicians.¹⁰⁵

These factors may partially explain why children who come into contact with the child welfare system, particularly those who reside in foster care, are prescribed psychotropic drugs more frequently than youth in the general population.¹⁰⁶ Using National Survey of Child and Adolescent Well-Being (NSCAW) data, Raghavan et al., reported in 2005, that approximately 14 percent of youth nationwide were prescribed at least one psychotropic drug within a year of coming into contact with the child welfare system/Child Protective Services.¹⁰⁷ Drawing from the same data source, it was estimated that nearly a quarter of youth (22 percent) involved in child welfare services received psychotropic medications over a 3-year period.¹⁰⁸ A General Accounting Office (GAO) report using Medicaid claims from five states found that 21 to 39 percent of children in foster care received a prescription for psychotropic medication in 2008, compared with 5 to 10 percent of children not in foster care. A more recent study using NSCAW data from 2008-2010 found that 11.7 percent of child-welfare involved children received psychotropics, with 29.1 percent of foster children receiving at least one medication.¹⁰⁹

While NSCAW data from 2008-2010 suggests the rate of antipsychotic utilization is “low” (6.4 percent of children in out-of-home placements),¹¹⁰ studies consistently find a link between foster care placement and the prescription of antipsychotics. The risk of a youth residing in foster care being prescribed antipsychotics was found to be 4.1 times more likely.¹¹¹ In a recent (and very large) study of Medicaid claims data, foster care more than doubled the risk of receiving antipsychotics, even after controlling for psychiatric diagnosis.¹¹² A recent report described the rate of antipsychotic utilization overall as “low” (6.4 percent of children in out-of-home placements).

Polypharmacy and Excessive Dosing

The practice of prescribing more than one class of drug to a child, for example an antipsychotic and a stimulant, or of prescribing multiple drugs from the same drug class to one child—known generally as “polypharmacy” or “concomitant prescription”—has also become increasingly common. It was estimated that this practice increased by over 750 percent in the general child population between 1987 and 1996,¹¹³ and of all instances of office-based visits to physicians reported from 1996-2007 that resulted in use of at least one psychotropic drug, 19 percent included prescriptions from more than one class of drug.¹¹⁴ The rapid increase in polypharmacy has raised public and professional concern, as it is generally agreed upon in the literature that psychotropic polypharmacy with children introduces potentially serious health risks that have not been sufficiently evaluated in research.^{115,116} There is no clear singular answer to why polypharmacy rates have risen, but the most obvious answer is that clinicians feel comfortable prescribing medication cocktails and find them of benefit based on their clinical experience.

Data also show that polypharmacy is more common among children who interact with child welfare services. Children residing in some type of foster care, or out-of-home care, are a subpopulation of youth involved in the child welfare system who are particularly vulnerable to potentially excessive or harmful psychotropic drug prescribing practices. There is also substantial evidence that children residing in foster care are at even greater risk of receiving polypharmacy and other potentially unsafe prescribing practices than the broader low socioeconomic status and child welfare populations. In the Zito et al. study of polypharmacy prevalence,¹¹⁷ approximately 72 percent of medicated foster youth were reported to receive more than one psychotropic drug, and over 41 percent of these children received medications from three or more different drug classes per day. Moreover, the 2011 Medicaid study found that as many as 41 percent of children in foster care who took any psychotropic medication received three or more psychotropics within the same month, a level of use that requires screening, assessment, and close monitoring by a physician.

Children residing in some type of foster care, or out-of-home care, are a subpopulation of youth involved in the child welfare system who are particularly vulnerable to potentially excessive or harmful psychotropic drug prescribing practices.

The NSCAW data analysis from 2008-2010 found that the mean number of medications prescribed was 1.9.¹¹⁸ While only 3.1 percent of a child welfare sample was prescribed 3 or more psychotropic medications, 13 percent of children in out-of-home/foster care placements were receiving polypharmacy of this sort.¹¹⁹

Children in foster care are also more likely to be prescribed psychotropic drugs for less clinically severe symptoms, suggesting these medications are used to manage the behaviors and emotions of foster children more so than in the non-child-welfare population.^{120,121,122}

Oversight of Psychotropic Drug Administration in Florida's Child Welfare System

Per the Child and Family Service Improvement and Innovation Act (P.L. 112-34), states must include "a psychotropic medication oversight plan in the "State Child and Family Service Plans" when children enter out-of-home care."¹²³ The US Department of Health and Human Services conducts periodic audits/reports of states' policies and their compliance, and provides resources to help states improve their drug oversight programs. Publication of the American Academy of Child and Adolescent Psychiatry's (AACAP) best principles guidelines is an example.^{124,125} Additionally, passage of the Fostering Connections to Success and Increasing Adoptions Act (Public Law 110-351) in 2008 and the Child and Family Services Improvement and Innovation Act (Public Law 112-34) in 2011 requires states to establish protocols for the use and oversight of psychotropic medications with foster children as a condition for receiving some types of federal child welfare funding.¹²⁶ In its recommendations for best practices, the AACAP categorizes psychotropic drug oversight policy areas broadly into the categories of consent/authorization, consultation, monitoring, and resources/information sharing.^{127,128}

Authorization and Consent Policies in Florida

Screening/Evaluation The AACAP best principles guideline recommends that "every youth in state custody should be screened and monitored for emotional and/or behavioral disorders. Youth with apparent emotional disturbances should have a comprehensive psychiatric evaluation."¹²⁹ In Florida, the Comprehensive Behavioral Health Assessment (CBHA) serves the purpose of a screening, with DCF Operating Procedure No. 155-10/175-40 stating "All children entering out-of-home care ages birth through 17 years who are Medicaid eligible are to be provided a CBHA" (p. 2-1) and that, while the CBHA is not a psychiatric assessment, the goal of the DCF is that the CBHA is used "in developing the dependency case plan, including addressing the child's and family's mental health service needs" (p. 2-2). The CBHA is described as a "psychosocial assessment that allows a comprehensive look at a child's behavioral health needs."¹³⁰ A referral "must be made within 7 days after the child comes into care (typically date of the shelter hearing). The assessor must complete the CBHA within 24 days of the referral."¹³¹

Psychiatric evaluation referral and medical report Unless a child is in a crisis stabilization unit (CSU), residential treatment facility, or hospital, a psychiatric evaluation referral must be submitted, and a medical report completed, before a child is administered a psychotropic drug. The medical report includes information about:

- The child's age, height, weight, and gender.
- The information that the physician conducting the report was given about the child's mental health prior to evaluation (e.g., school based services the child received, prior assessments, and other records).
- The drug(s) the physician is prescribing, the dosage range, starting date, the estimated length of time for which the child will take the drug, and the possible adverse effects
- The child's diagnosis for which the drug is being given and what symptoms/behaviors the drug is intended to address, as well as what results are expected from the child taking the drug.
- Recommendations for other forms of treatment (i.e., psychosocial) to be used in conjunction with the drug(s).
- How information about the drug was provided to the child's parent or caregiver and whether it was discussed.
- Information about whether alternatives to drug treatment are available, if they have been attempted before prescribing a psychotropic drug, and if not, why these were not attempted.

Informed consent process In Florida, administration of a psychotropic drug to a child is considered an "extraordinary procedure," as opposed to what is deemed by the state Department of Children and Families to be "ordinary and necessary care," such as (non-psychiatric) medical and dental visits (Rule 65C-35 [section .007], effective 3/17/2010). The policy for consent in Florida's child welfare system comes from the DCF (CF Operating Procedure No. 175-98) and requires that a birth parent, adoptive parent, or legal guardian give informed consent for their child to receive any psychotropic medication. Minimally, the information considered to be necessary for informed consent to administer a psychotropic drug to a child includes:

- A copy of the child's medical report
- How the drug will be administered and monitored
- An explanation of the drug and its intended purpose

- The known adverse effects, risks, and contraindication of the drug
- Precautions regarding drug interactions
- Possible adverse effects of stopping use of the drug
- Options for alternative (i.e., non-pharmacological) treatment(s)
- The prescribing physician's plan for eventual reduction and/or discontinuation of the drug, if appropriate

Additionally, age and developmentally appropriate information regarding the psychotropic drug(s) to be administered should be provided,¹³² and assent obtained from the child in question, whenever possible.¹³³ Changes to a child's medication(s), including dosage changes exceeding what was originally consented to, require obtaining informed consent as well.¹³⁴

If a child does not have a birth parent, adoptive parent, or legal guardian, consent for the child to receive psychotropic medication must be obtained through a court order. A court-ordered hearing and approval is also required to administer a psychotropic drug to a child if his or her parent or guardian's legal rights have been terminated (TPR); if the parent or legal guardian's location or identity is unknown; or if the parent or legal guardian refuses to participate.¹³⁵ In cases where the child's legal guardian is unknown, refuses participation, or in cases where parents with rights intact "decline to approve administration of psychotropic medication" or in cases of TPR, DCF policy states that "[i]f any party to the case believes that administration of the medication is in the best interest of the child, then authorization to treat with psychotropic medication must be pursued through court order."¹³⁶ In cases where authorization to administer a psychotropic drug to a child is obtained through a court order, the court order and a medical report must be submitted, and the court order approved, before a child can be administered the drug.¹³⁷ Court approval is also required when a child is placed in out-of-home care in a correctional facility or residential treatment center (i.e., workers from these facilities cannot give express and informed consent for a child to be given a drug).

Preconsent review for prescription for two or more psychotropic drugs Since 2010, Florida has mandated a pre-consent review process that must be followed for children in out-of-home placement under the age of 11 years who are prescribed two or more psychotropic drugs.¹³⁸ If upon assessment, a physician determines that a child needs two or more psychotropic drugs, a Psychotropic Medication Treatment Plan Review form must be completed by the prescriber and reviewed by a consultant child psychiatrist within two business days of the date the child is prescribed two or more psychotropic drugs. These reviews are negotiated through a contract between the DCF and the University of Florida College of Medicine Department of Psychiatry. The recommendation from the consulting psychiatrist obtained in the preconsent review is intended to inform whoever has legal authority to consent for the child to be administered a psychotropic drug (i.e., a parent/legal guardian or the judge if consent is obtained through court order). While it is not explicitly stated in CF Operating Procedure No. 175-98, a memorandum dated December 2, 2010, notes that parents or legal guardians whose rights are still intact may waive pre-consent review for their children.¹³⁹

Prior authorization for Medicaid reimbursement A prior review/authorization process was implemented in April 2008 by the Agency for Health Care Administration's Florida Medicaid Drug Therapy Management Program for Behavioral Health. Some prescriptions require a case-by-case (i.e., individual) review by a child psychiatrist other than the original prescribing provider before the cost of the drug is reimbursed by Medicaid. This process is overseen by child psychiatry reviewers at the University of South Florida. From 2008 to 2011, the number of applications for antipsychotics to very young children (<6) dropped 35 percent.^{140,141} This protocol appears to have influenced improvements in the use of antipsychotics in the broader Medicaid population, leading to other pre-authorization requirements (e.g., antipsychotics for older children, antidepressants in children <6). Such prescriptions require that psychosocial treatment precede the use of medication.¹⁴²

Administration of a psychotropic drug without consent or court order However, a child may be administered a psychotropic drug without express and informed consent or a court order (referred to as "emergency administration of psychotropic medication,"¹⁴³ if he or she is admitted to "any hospital, crisis stabilization unit (CSU), or SIPP [Statewide Inpatient Psychiatric Program]". Parent/guardian express informed consent or court order can also be waived in instances where a child's prescribing physician certifies that withholding the prescribed drug would "more likely than not cause significant harm to the child".¹⁴⁴ In both cases, administration of psychotropic drugs without consent or court order, a motion for court order (or parental authorization in the second instance of not withholding a drug) must be filed within three business days of administering the drug. A small number of children are documented in the Florida Safe Families Network (FSFN) as having received medication without consent—from a weekly average of 0.19 percent in 2011 to 1.4 percent in 2016. This represents a substantial improvement in consent procedures since 2009.¹⁴⁵

Consultation Since 2004, the MedConsultLine has been available for "families, guardians, and the courts to consult with board certified psychiatrists via telephone".¹⁴⁶ The MedConsult Line offers assistance to decision makers dealing with psychotropic medication. The service is provided by the College of Medicine at the University of Florida.

Monitoring Caregivers of children receiving psychotropic medications must maintain and submit monthly logs of all medications administered to the child, including dates and times of administration.¹⁴⁷ Children in out-of-home care receiving psychotropic drugs are also monitored by DCF's submission of each child's "medical and behavioral status" at judicial review hearings.¹⁴⁸ Data on each child's medical profile, medications (both active and discontinued), mental health profile (including most recent CBHA), and

medical history are recorded in the FSFN. Information on prescribed psychotropic drugs is to be entered into the FSFN within three business days of the child starting the drug. Child-level psychotropic medication data are reported and monitored for youth in the FSFN and published in a Psychotropic Medication Report that is posted weekly on the DCF’s Child Welfare Data Repository, and via ad hoc reports.¹⁴⁹

Information Sharing/Resources Florida’s Center for Child Welfare at the University of South Florida maintains a website with the documents recommended by the US Government Accountability Office, such as informed consent documents. The Psychotherapeutic Medication Guide¹⁵⁰ is also available, as recommended by AACAP. As previously mentioned, the FSFN aggregate reports on psychotropic medications are available weekly.

Assessment of Florida In 2011, the GAO rated Florida’s consent laws according to the AACAP’s Best Practice Guidelines, finding that Florida met the “Recommended” level of guideline, outperforming Maryland, Massachusetts, and Oregon. Per the GAO, Florida could meet the “Ideal” level of guideline (as Texas already does) by enhancing training for child welfare professionals on the topic of psychiatric medications, in order to “help them become more effective advocates for children in their custody”.¹⁵¹ The GAO report praised many aspects of how Florida handles the issue of psychotropic medications— including the FSFN medication data available to the public on the web, pre-authorization for antipsychotics, and the MedConsultLine. These policies are sometimes cited as exemplars by other states as they develop their own policy documents for addressing the issue of psychotropic medication in child welfare.

As of 2008, the GAO reported that 22 percent of foster children in Florida were prescribed psychotropic drugs.¹⁵² This included 5.3 percent of children aged 0-5, 31.2 percent of those age 6-12, and 36.8 percent of those age 13-17. The proportion of medicated children¹⁵³ within the FSFN database from May 2010 – December 2016 are represented below in Figure 1. As Figure 1 demonstrates, the proportion of Florida children in out-of-home placements who are taking at least one psychotropic drug has been declining since June of 2013. This includes decreases in the proportions of medicated children for each separate age category for which data are provided (ages 0-5 years, 6-12, and 13-17). The number of medicated children throughout 2016 has ranged from 2,491-2,636. The mean proportion¹⁵⁴ of medicated children in 2016 was 11.2 percent; broken down by age, this is 1.2 percent of 0-5 year-olds, 17.8 percent of 6-12 year olds, and 26.9 percent of 13-17 year-olds.

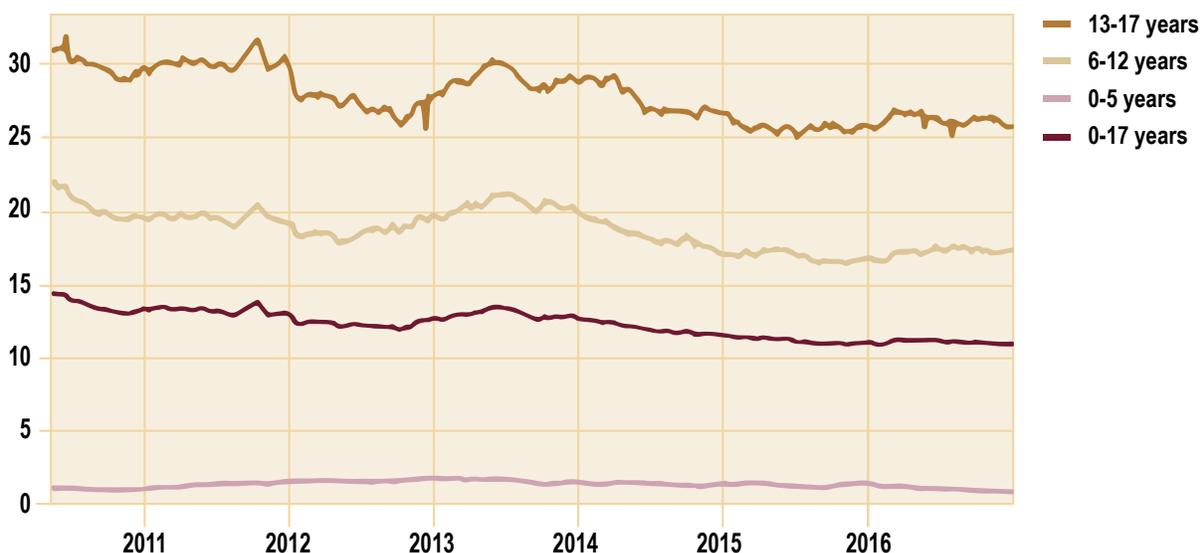


FIGURE 1: PERCENTAGE OF CHILDREN PRESCRIBED A PSYCHOTROPIC MEDICATION IN FLORIDA, PER FSFN, MAY 2010-DECEMBER 31, 2016, BY AGE OF CHILD.

SOURCE: www.dcf.state.fl.us/initiatives/GMWorkgroup/reports.asp

There are sharp differences in the rate of medication depending on placement setting. In 2016, children in licensed substitute care receive medication at much higher rates than those placed in relative/non-relative care (i.e., for ages 0-17, 18.6% vs. 5.2%; for ages 0-5, 2.0% vs. 0.7%; for ages 6-12, 27.6% vs. 10.3%; for ages 13-17, 36.1% vs. 11.3%).

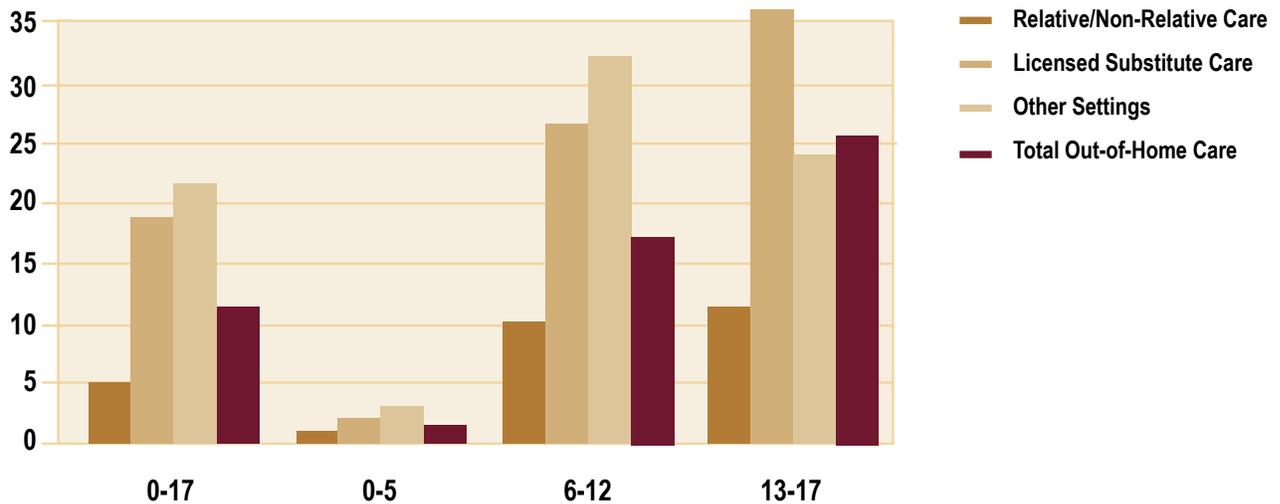


FIGURE 2: PERCENTAGE OF CHILDREN PRESCRIBED A PSYCHOTROPIC MEDICATION IN FLORIDA IN 2016, PER FSN, BY AGE OF CHILD, BY PLACEMENT SETTING.

SOURCE: www.dcf.state.fl.us/initiatives/GMWorkgroup/reports.asp

It is not possible to establish an ideal rate of medication utilization, and difficult to directly compare some states as they often use differing operationalizations and age categorizations. However, comparing Florida to other states is possible to a limited degree, and may be useful if approached with inferential caution. In the recent past, several states have reported higher overall medication rates than Florida. Texas reported medication rates around 20 percent from 2009-2013. A 2012 chart audit in Michigan found a 28 percent medication rate. In 2012, Colorado reported a 25.65 percent rate of medication among children in foster care, and a 4.82 percent rate among 0-5 year-olds. More recently, from April 2014 – March 2015, California reported that 9.6 percent of children in foster care received psychotropic medication, including 0.8 percent of 0-5 year-olds. In the same time period, Florida’s mean medication rate based on FSN data was 11.2 percent (for age 0-17) and 1.2 percent (for age 0-5). Such comparisons are limited by the nature of the available data, and continuing concerns regarding the use of psychotropic medications with Florida’s child welfare clients are clearly justified. However, Florida is clearly not an outlier in terms of medication utilization, and, in fact, has experienced a sustained, if modest decrease in the use of psychotropic medications in the child welfare population.

Recommendations for Research, Practice, and Policy

The following five recommendations are proposed for consideration:

- 1) *Systematically and rigorously measure the degree to which current policies are well-implemented throughout the Florida system.* Based on these study results, fine-tune the implementation of Florida’s existing policies and procedures regarding psychotropic drugs.
- 2) *Strengthen the role of trauma-informed psychosocial services in the child welfare system and evaluate the service outcomes.* Optimally, service outcomes should be evaluated through assessing the risk:benefit ratios to children in the child welfare system. Cost-benefit analysis and other outcome studies could help assess whether an emphasis on trauma-informed, psychosocial strategies with child welfare clients prove to be more or less costly in the long-term as compared to more psychotropic medication use and other treatment-as-usual.
- 3) *Future studies in Florida should collect additional data on how frequently psychotropic medication withdrawal is attempted.* Existing scientific outcome studies of the use of psychotropic medication show that it is primarily associated with short-term benefits; longitudinal data showing effectiveness are rare. Research should be designed to evaluate the range of opportunities for medication withdrawal. Among children in stable placements, it will be important to compare outcomes among children that are slowly and conservatively withdrawn from psychotropic medication with those children who remain on medication.

- 4) *The effectiveness of informed consent and approval processes should also be studied.* At the least, this will involve careful and reiterative reviews of the informational materials used in the process of informing patients, prescribing or judicial decision-making. Ensure that such materials reflect the most current scientific data on the potentials risks and benefits of psychotropic medication to children.
- 5) *Enhanced tracking and reporting of data regarding psychotropic medication may be beneficial.* At present, the publically available FSFN data aggregates all children as “medicated” or “not”, a low-resolution look at the issue (e.g., a sleeping medication and antipsychotic are counted as equivalent). A more refined form of data reporting could be useful. Additionally, the number of children who enter the child welfare system on medication is another potentially useful metric.
- 6) *Implement training for child welfare professionals on the topic of psychotropic medications, and scientifically evaluate the training and practice outcomes.* Training can only improve child welfare outcomes if it can be demonstrated, first, that practitioners actually adopt the new approaches and then apply them with fidelity; and, second, that child outcomes are positively enhanced by these modified practices.

Appendix A: Reliability Estimates for Childhood Diagnoses from the DSM Field Trials

Disorder	Agreement Between Clinicians ^a	95% Confidence Interval ^b
Disruptive Mood Dysregulation Disorder ^c	25%	15 – 36%
Major Depressive Disorder ^c	28%	15 – 41%
Oppositional Defiant Disorder ^c	40%	18 – 61%
Attention-Deficit Hyperactivity Disorder ^c	61%	51 – 71%
Conduct Disorder ^d	61%	Not Reported
Autism Spectrum Disorder ^c	69%	58 - 79%
Bipolar I Disorder ^c	Unable to Estimate	
Bipolar II Disorder ^c	Unable to Estimate	
Post-Traumatic Stress Disorder ^e	Unable to Estimate	

^aAgreement refers to kappa values, a measure of chance-corrected inter-rater agreement.

^bThis is interpreted as follows: Our best estimate of inter-rater agreement for Disruptive Mood Dysregulation Disorder is 25 percent, but there is some uncertainty, and there is a 95 percent probability that the true value lies between 15 and 36 percent.

^cResults reported in the DSM-5 field trials (see reference 47).

^dDSM-5 field trials were unable to estimate, but 61% agreement was found in the DSM-III field trials in 1980 (see reference 44).

^eDSM-5 field-trials were unable to estimate; perfect agreement was found for anxiety disorders in DSM-III in 1980, but this was an extremely small subsample (~3 children; see p. 471, DSM-III) and it is unknown if any of these children were diagnosed with PTSD.

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