


# Antipsychotic Prescriptions for Children Aged 5 Years or Younger: Do We Need Policy Oversight Standards?

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## Abstract

The use of antipsychotics in very young children is of concern given the lack of empirical evidence in their efficacy and long-term impact on children's health. This study examined the prescription of antipsychotics among children aged  $\leq 5$  years enrolled in a state Medicaid program. Secondary data analysis was conducted using the Medicaid administrative data of a southeastern state. Using SAS 9.3, descriptive statistics were performed to examine socio-demographic characteristics, psychiatric diagnoses, off-label use, receipt of medications from multiple psychotropic drug classes, and receipt of non-pharmacologic psychiatric services among children aged  $\leq 5$  years who received antipsychotic prescriptions in calendar year (CY) 2011. A total of 112 children in the target age group received antipsychotics in CY 2011, the most common prescription being risperidone. The most common listed psychiatric diagnosis was attention deficit hyperactivity disorder. Two in five children received antipsychotics for off-label use. Three in four children also received medications from at least one other psychotropic drug class. More than half did not receive adjunct psychiatric services. State-level policies offering specific guidance and recommendations for antipsychotic use among very young children are urgently needed. Future research is warranted to examine long-term impact of such practices on children's growth and development.

## Keywords

psychiatry, psychotherapy, sociology of health and illness, sociology of mental health, public administration and public policy

## Introduction

Use of antipsychotic medications has been steadily increasing in the pediatric population over the last two decades. However, many experts have raised concerns over this trend given the limited research evaluating the efficacy and long-term impact of these medications on children's growth and development. Pre-school children are particularly vulnerable in this context, and increasing trend of antipsychotic prescriptions among them is of particular interest. The vulnerability further increases if the child is enrolled in Medicaid given the unique socio-economic circumstances. This article presents the findings of a cross-sectional study examining the use of antipsychotics among children aged 5 years or younger (referred to as very young children) in a Medicaid program of a southeastern state in the United States. It seeks to expand our understanding of antipsychotic medication use in very young children enrolled in the state Medicaid program, particularly in terms of psychiatric diagnoses, off-label use, multi-class treatments, and use of adjunct therapy options. Such understanding is critical not only from the quality of care and health outcomes perspectives but also from an economics perspective as Medicaid carries a burden of payment for pharmacological treatments and spends more on antipsychotic medications than any other class of drugs.

## Background

Several studies indicated a growing trend of antipsychotic prescriptions in children and adolescents over the years, especially because second-generation antipsychotics have similar efficacy, but significantly lower rates of extrapyramidal side effects compared with their first-generation counterparts (Crystal, Olfson, Huang, Pincus, & Gerhard, 2009; Medicaid Medical Directors Learning Network [MMDLN], 2010). Even in young children, the rates of antipsychotic prescriptions have increased significantly (Constantine et al., 2012; Olfson, Crystal, Huang, & Gerhard, 2010). Some population-based studies indicated that the most significant increases in psychotropic drug prescriptions among Medicaid-enrolled preschoolers occurred in atypical antipsychotic use (Cooper, Hickson, Fuchs, Arbogast, & Ray, 2004; Patel et al., 2005; Zito et al., 2007). In an examination of antipsychotic medication trends in very young privately insured children (aged 2–5 years), researchers found the

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increase in the annual rate of antipsychotic use per 1,000 children from 0.78 in 1999-2001 to 1.59 in 2007 with a significant increase in children diagnosed with multiple psychiatric disorders (Olfson et al., 2010). Another study by Constantine and colleagues examining exposure to antipsychotics in children initiating the treatment before 6 years of age found that these children are at risk for extensive medication exposure due to long-term prescribing of antipsychotics and medications from other psychotropic drug classes (Constantine et al., 2012). These studies highlight the need for examining antipsychotic prescription patterns among very young children with increased vulnerability, such as those enrolled in the Medicaid program. Medicaid, the single largest source of health care coverage in the United States, is the government insurance program that provides health care coverage for persons, including children, with low incomes and is administered by the states within broad federal guidelines.

Clinically questionable prescription practices related to psychotropic medications including antipsychotics among Medicaid recipients have been noted by some researchers (Essock et al., 2009; MMDLN, 2010). Such questionable practices include the use of antipsychotics in young (age  $\leq 5$  years) children (MMDLN, 2010), use of multiple psychotropic medications (Comer, Olfson, & Mojtabai, 2010; Constantine, Boaz, & Tandon, 2010), off-label use of antipsychotics (Crystal et al., 2009; Leslie & Rosenheck, 2012), and lack of adjunct non-pharmacological psychiatric services (Harris, Sorbero, Kogan, Schuster, & Stein, 2012; Olfson et al., 2010). The MMDLN recommends the use of antipsychotics in children aged 5 years or younger and use of multiple mental health drugs any time during a calendar year (CY) as measures of quality and safety issues in authorizing mental health treatment (MMDLN, 2010). Use of antipsychotics in young children is a serious consideration given the lack of consistent empirical evidence on treatment efficacy as well as its potential negative impact on a highly sensitive and developing/maturing central nervous system (Gleason et al., 2007; MMDLN, 2010). This course in prescriptions of multiple psychotropic medications that are often used to treat complex symptomatology in children (Comer et al., 2010; Constantine et al., 2010), despite limited research on safety and efficacy of such multi-drug regimens (Safer, Zito, & DosReis, 2003), requires examination and policies to help prescribing patterns.

Use of medications for treating conditions other than those approved by the Food and Drug Administration (FDA), also referred to as off-label use, is common in pediatric populations (American Academy of Child and Adolescent Psychiatry [AACAP], 2009; Shah et al., 2007), specifically for antipsychotic medications (Crystal et al., 2009; Leslie & Rosenheck, 2012). The FDA has approved the use of antipsychotics in children and adolescents for schizophrenia, behavioral symptoms of autism, Tourette's syndrome, and bipolar disorder (Crystal et al., 2009). However, once

approved by the FDA, clinicians can prescribe these medications, based on their judgment, for conditions that may not have received FDA approval (Leslie & Rosenheck, 2012). A retrospective analysis of the administrative data from 42 state Medicaid programs revealed that nearly 58% of clients receiving antipsychotics received them for off-label use, and the proportion was even higher (76%) among persons younger than 21 years (Leslie & Rosenheck, 2012). Given the adverse metabolic effects on carbohydrate and lipid metabolisms, increasing off-label use of second-generation antipsychotics in very young children is a serious concern.

Another commonly cited concern is the over-reliance on pharmacological treatments without trying other psychiatric services, including psychotherapy. A recent study examining concurrent mental health therapy among Medicaid youth starting antipsychotic medications found that nearly a third of children did not receive non-pharmacological psychiatric or behavioral services (Harris et al., 2012). Olfson and colleagues (2010) also found that, despite increased use of antipsychotics in very young children, provision of non-pharmacologic psychiatric services remains limited. The Preschool Psychopharmacology Working Group of the AACAP recommends a trial of psychosocial treatment to precede psychopharmacological treatments in young children (Gleason et al., 2007).

The purpose of this study was to examine the use of antipsychotic medications among children aged 5 years or younger in a Medicaid program of a southeastern state who received antipsychotic prescriptions in CY 2011. In addition to examining characteristics of young children receiving antipsychotics, the study also examined (a) the most frequently listed psychiatric diagnoses, (b) off-label use of antipsychotics, (c) prescriptions of medications from multiple psychotropic drug classes, and (d) receipt of psychiatric services in addition to medications among the sample.

## Method

### *Sample and Setting*

A cross-sectional secondary data analysis was conducted using a subset of Medicaid administrative data from a southeastern state. The sample included children aged 5 years or younger who received antipsychotic medications in CY 2011. The study was exempt from Institutional Review Board (IRB) review due to use of a de-identified administrative data set.

**Variables.** The variables of interest were extracted from recipient family file and physician (A), pharmacy (D), and hospital (Z) claims for each beneficiary for CYs 2009-2011. Socio-demographic variables as of December 31, 2011, included age (1-3 years, 4 years, or 5 years), sex (male or female), race (White, African American, or Other, including Asian, Native American, multi-racial, and unknown race),

status (foster care or non-foster care), area of residence (rural or urban), and social deprivation measured by the Palmetto Small Area Deprivation Index (Palmetto-SADI; López-De Fede, Stewart, Hardin, Mayfield-Smith, & Keck, 2012). The Palmetto-SADI is similar to the Townsend Index (Townsend, Phillimore, & Beattie, 1998) that categorizes place of residence into low-moderately deprived area, highly deprived urban area, and highly deprived rural area appropriate to the southeastern United States. Each beneficiary was classified into two categories based on their clinical risk group (CRG) levels. The mild-to-moderate CRG category included levels less than 5, whereas the severe-to-catastrophic CRG category included levels 5 or above. The International Classification of Diseases version 9 (ICD 9) codes were used to identify eight psychiatric diagnostic categories: attention deficit hyperactivity disorders (ADHD; 314), adjustment disorders (309.0 and 309.1), anxiety disorders (300.0), disruptive behavior disorders, mood disorders, pervasive developmental disorders (PDD; 299.0-299.8), psychotic disorders, and substance abuse disorders. Four of these eight categories included additional diagnoses. Specifically, the disruptive behavior disorders included conduct disorder (312) and oppositional defiant disorder (313.81); mood disorders included bipolar disorder (296), depressive disorder not classified elsewhere (311), and dysthymic disorder (300.4); psychotic disorders included schizophrenia (295 and 299.9), delusional disorders (297), and other non-organic psychoses (298); and substance abuse disorders included alcohol dependence syndrome (303), drug dependence (304), and non-dependent drug abuse (305). We used ICD 9 codes instead of *Diagnostic and Statistical Manual of Mental Disorders (DSM)* criteria because the Medicaid claims data do not include information on the latter. A child was classified as having a psychiatric diagnosis if any of the above diagnoses was listed on the claims. Using a broad definition, the use of antipsychotic medication was categorized as “indicated,” if the child had any of the following diagnoses: psychotic disorder, bipolar disorder, or PDD. All other listed psychiatric diagnoses as well as those without any listed diagnoses were categorized as “off-label” use of antipsychotics. Receipt of non-pharmacologic psychiatric services was dichotomized into “yes” or “no” depending on whether the child received any of the services identified by selected Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes in 2011 or the 2 years preceding it (S8180, S8181, S8184, S8185, S8186, H2029, 90804, 90806, 90808, 90810, 90812, 90814, 90816, 90818, 90821, 90823, 90826, 90828, 90849, 90853, 90857, 90870, 90875, 90876, 90880, 90901, 96100, 96151, 96152, 96153, 96154, 96155, 90846, 90847, and 99241).

## Analysis

Descriptive statistics were performed to describe characteristics of children aged 5 years or younger who were enrolled in

**Table 1.** Characteristics of Medicaid Children ≤5 Years Living in a Southeastern State and Receiving Antipsychotic Prescription(s) in Calendar Year 2011 (N = 112).

Characteristic	Frequency	%
Status		
Non-foster care	105	93.75
Foster care	7	6.25
Age (years; M = 4.62, SE = 0.06)		
1-3	8	7.14
4	26	23.21
5	78	69.64
Sex		
Male	87	77.68
Female	25	22.32
Race		
White	52	46.43
African American	17	15.18
Others	43	38.39
CRG		
Healthy/moderate	3	2.68
Severe/catastrophic	109	97.32
Residence		
Urban	75	66.96
Rural	37	33.04
Social deprivation (Palmetto-SADI)		
Low/moderate deprivation	98	87.50
Rural deprivation	9	8.04
Urban deprivation	5	4.46
Listed psychiatric diagnosis		
Yes	107	95.54
No	5	4.46
Number of psychotropic drug classes prescribed		
One class	30	26.79
Two classes	55	49.11
Three classes	25	22.32
Four classes	2	1.79

Note. CRG = clinical risk group; Palmetto-SADI = Palmetto Small Area Deprivation Index.

a state Medicaid program and who received antipsychotic prescriptions in 2011. In bivariate analysis, we also examined characteristics of children who received antipsychotics as off-label prescriptions and those who did not receive any psychiatric services other than medications. Furthermore, we examined the commonly listed psychiatric diagnoses and the psychotropic drug classes prescribed to these children. All analyses were conducted using SAS® version 9.3.

## Results

Out of 3,788 state Medicaid children aged 5 years or younger who received psychotropic medication prescription(s) in CY 2011, 112 (2.96%) received prescription(s) for antipsychotic medications. Table 1 describes the characteristics of these children. The average age of the children was 4.6 years with

**Table 2.** Numbers of Psychiatric Diagnoses and Prescribed Psychotropic Drug Classes in Medicaid Children ≤5 Years Living in a Southeastern State and Receiving Antipsychotic Prescription(s) in Calendar Year 2011 (*N* = 112).

Number of psychiatric diagnoses	Number of psychotropic drug classes prescribed: <i>n</i> (%) <sup>a</sup>		
	Total	Antipsychotics only (mono-class therapy)	≥Two psychotropic classes (multi-class therapy)
0	5 (4.46)	1 (20.0)	4 (80.0)
1	41 (36.61)	20 (48.78)	21 (51.22)
2	44 (39.29)	9 (20.45)	35 (79.55)
3	17 (15.18)	0 (0.00)	17 (100.00)
≥4	5 (4.46)	0 (0.00)	5 (100.00)

Note. <sup>a</sup>Percent indicates row percent.

**Table 3.** Listed Psychiatric Diagnoses in Medicaid Children ≤5 Years Living in a Southeastern State and Receiving Antipsychotic Prescription(s) in Calendar Year 2011 in the Order of Frequency (*N* = 112).

Psychiatric diagnosis	Frequency <sup>a</sup>	%
ADHD	65	58.04
Disruptive behavior disorders	50	44.64
PDD	37	33.04
Mood disorders	31	27.68
Adjustment disorders	13	11.61
Anxiety disorders	4	3.57
Psychotic disorders	2	1.79

Note. ADHD = attention deficit hyperactivity disorder; PDD = pervasive developmental disorder.

<sup>a</sup>The sum of frequencies is >112 as some children had multiple diagnoses.

almost 70% of children aged 5 years. The sample was predominantly male (~78%). Approximately two-thirds of the children lived in urban areas. Among those who received antipsychotics, almost a quarter of the children received only antipsychotic medications, whereas about half received medications from another psychotropic drug class and another quarter received medications from two or three additional psychotropic drug classes.

As indicated in Table 1, the overwhelming majority of children had at least one psychiatric diagnosis listed in their claims (*n* = 107; 95.5%). Nearly 60% of children had received two or more psychiatric diagnoses. As the number of diagnoses increased, prescription of medications from multiple psychotropic drug classes also increased (Table 2). Approximately three in four children receiving antipsychotics also received medications from other psychotropic drug classes (*n* = 82; 73.2%). The most common psychotropic drug class combination was antipsychotics and ADHD medications (*n* = 43; 38.4%), followed by antipsychotics, anticonvulsants, and ADHD medications (*n* = 16; 14.3%). The most commonly prescribed antipsychotic medication was risperidone, followed by aripiprazole. The less frequently prescribed antipsychotics included quetiapine, ziprasidone, olanzapine, and thioridazine.

Table 3 describes the listed psychiatric diagnoses among the sample. The most common listed diagnosis was ADHD

(58%), followed by disruptive behavior disorders (45%) and PDD (33%). As noted earlier, more than half of the children had received two or more psychiatric diagnoses.

Out of a total of 112 children who received antipsychotic medications, more than half of the children did not receive psychiatric services (*n* = 61; 54.5%), and nearly two in five children received the antipsychotics for off-label use (*n* = 43; 38.4%). Characteristics of children receiving antipsychotics for off-label use and those who did not receive non-pharmacological psychiatric services are shown in Table 4. Off-label use of antipsychotics was more frequent in boys, White children, children with severe-to-catastrophic CRGs, and those living in urban areas. A similar pattern followed for the non-receipt of psychiatric services except for racial differences with a greater proportion of children from Other races (all races excluding White and African American) not receiving psychiatric services.

## Discussion

This study examined characteristics of young children enrolled in a state Medicaid program who received antipsychotic prescriptions in CY 2011 as well as patterns of prescriptions. Although a small proportion of young children who received any psychotropic medications received antipsychotics, the findings revealed some concerning practices,



**Table 4.** Off-Label Use of Antipsychotics and Non-Receipt of Psychiatric Services in Medicaid Children ≤5 Years Living in a Southeastern State and Receiving Antipsychotic Prescription(s) in Calendar Year 2011.

Characteristic	Total (N = 112) n (%) <sup>a</sup>	Off-label use (n = 43) n (%) <sup>a</sup>	No psychiatric services (n = 61) n (%) <sup>a</sup>
Sex			
Male	87 (77.68)	35 (81.40)	49 (80.33)
Female	25 (22.32)	8 (18.60)	12 (19.67)
Race			
White	52 (46.43)	23 (53.49)	22 (36.07)
African American	17 (15.18)	11 (25.58)	7 (11.48)
Others	43 (38.39)	9 (20.93)	32 (52.46)
CRG			
Healthy/moderate	3 (2.68)	2 (4.65)	3 (4.92)
Severe/catastrophic	109 (97.32)	41 (95.35)	58 (95.08)
Residence			
Rural	37 (33.04)	12 (27.91)	24 (39.34)
Urban	75 (66.96)	31 (72.09)	37 (60.66)
Social deprivation (Palmetto-SADI)			
Low/moderate deprivation	98 (87.50)	39 (90.70)	56 (91.80)
Rural deprivation	9 (8.04)	2 (4.65)	4 (6.56)
Urban deprivation	5 (4.46)	2 (4.65)	1 (1.64)

Note. CRG = clinical risk group; Palmetto-SADI = Palmetto Small Area Deprivation Index.

<sup>a</sup>Percent indicates column percent.

including off-label use of antipsychotics, prescriptions for multiple psychotropic medications, and over-reliance on pharmacological treatment options. In general, young children receiving antipsychotics were more likely to be males, at least 4 years of age, and not in foster care. As expected, the overwhelming majority had complex medical conditions indicated by their severe-to-catastrophic CRG categories. Boys were more likely than girls to receive antipsychotics. The top three psychiatric diagnoses listed in the claims data were ADHD, disruptive behavior disorders, and PDD. These findings were consistent with the past research (Constantine et al., 2012; Olfson et al., 2010). Although nearly 96% of the children in our sample had indeed received some form of psychiatric diagnosis, it also reflects that 4% of the children had received antipsychotic prescriptions without any documented psychiatric diagnosis. Furthermore, one should also keep in mind that at such young age a firm diagnosis of a specific psychiatric disorder is often unreliable given that most psychiatric diagnoses are based on subjective evaluation of symptoms which may be simply a part of normal variation in behaviors among very young children.

We found that off-label use of antipsychotics was common in this sample. Our definition of off-label use may have underestimated the actual proportion of children receiving antipsychotics for off-label use. We used a broad definition based on approved indications for the antipsychotic use, which did not take into account the age for which the medication has been approved. As stated earlier, the most commonly prescribed antipsychotic medication was risperidone

followed by aripiprazole, whereas less frequently prescribed antipsychotics included quetiapine, ziprasidone, olanzapine, and thioridazine. According to the 2012 publication of the Agency for Healthcare Research and Quality (Christian et al., 2012), thioridazine is approved for all ages for treatment of schizophrenia; risperidone has been approved for children aged 5 years and older for autism spectrum disorders; while aripiprazole, the second most common prescription in our sample, has been approved only for children aged 6 years or older. Similarly, quetiapine and olanzapine have been approved for children aged at least 10 and 13 years respectively for schizophrenia and bipolar disorder. Ziprasidone has not been approved for the use in children. Our findings highlight the need to have an oversight on antipsychotic prescriptions in very young children enrolled in Medicaid.

It was concerning that nearly three out of four children receiving antipsychotics also received medications from at least one more psychotropic drug class. Furthermore, one in four children received medications from two other psychotropic drug classes in addition to the antipsychotics. This finding raises a serious alarm about potential negative impact on children's future growth and development. The developing brain is sensitive to the effects of psychotropic medications (Gleason et al., 2007). Given the rapid physical, physiological, and emotional growth and brain development among young children, it is critical to conduct long-term longitudinal studies to assess the impact of such multi-class regimens. The general consensus in experts is to try psychiatric services first before opting for the pharmacological

treatments in children (Gleason et al., 2007). However, our analysis revealed that more than half of the children did not receive any psychiatric services. This is a critical policy point. As an example, if the aggressive or disruptive behavior of a child is a result of family friction or hostile home environment, using antipsychotics may be an inappropriate choice as it will not address the underlying cause of the problem (Harrison, Cluxton-Keller, & Gross, 2012). Every attempt should be made to offer appropriate psychiatric services to children and their families before starting them on antipsychotics and other psychotropic medications. As noted earlier, the AACAP recommends a trial of psychosocial treatment to precede psychopharmacological treatments in young children (Gleason et al., 2007). This policy shift would minimize unnecessary reliance on medications and avert the potential negative impact on a child's growth and development resulting from inappropriate use of antipsychotics.

This study has several limitations. Given the cross-sectional nature of the study, it is not possible to identify any trends in antipsychotic prescriptions or establish causative pathways. Administrative data have their own limitations, including data entry errors and missing data, particularly on socio-demographic variables. We addressed this issue by limiting our sample to those records that have no missing values for these variables. Furthermore, the analysis presented here is only descriptive and does not include multivariate analysis. As previously noted, the study may have underestimated the use of antipsychotics for off-label indications as we did not take into account the age for which the antipsychotic has been FDA-approved. The study only described the prescription of medications from multiple psychotropic drug classes; it did not examine whether these medications were prescribed concurrently. It is possible that some cases may have received multiple medications concurrently, and it would be reasonable to expect such overlap as it is a common practice to offer a short trial on different medications if the response is not evident. However, given the young age of these children, exposure to medications from multiple psychotropic classes is still a concern. Finally, the study did not examine the types of providers who prescribed antipsychotics to young Medicaid children. Past research suggests that psychiatrists and pediatricians are the common prescribers of antipsychotics (Harpaz-Rotem & Rosenheck, 2006; Patel et al., 2006). It will be necessary to examine what types of providers are prescribing antipsychotics in very young children. Despite these limitations, the findings provide a good overview of the prevalence of antipsychotic prescriptions among young children enrolled in a state's Medicaid program and do have policy implications. Further research is needed to evaluate long-term health impact of initiation of antipsychotic medications at such young ages. Given that Medicaid is the major payer of antipsychotic prescriptions (Crystal et al., 2009), research is also needed in conducting cost-benefit analysis and assessing the financial burden on Medicaid.

## Conclusion

Although a small proportion of young children enrolled in a state's Medicaid program received antipsychotic prescriptions in CY 2011, the results identified serious concerns in prescription practices. A multi-agency and multi-disciplinary task force should be established to offer guidelines and recommendations for the use of antipsychotics in children aged 5 years or younger. State officials and policy makers should establish policies related to the oversight of antipsychotic prescriptions in children.

## Authors' Note

The views expressed in this article are solely the responsibility of the authors and do not necessarily represent the views of the South Carolina Department of Health and Human Services, Medicaid Program.

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