The Illinois Department of Children and Family Services Centralized Psychotropic Medication Consent Program: Monitoring the Use of Psychotropic Medications in Foster Children

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The Overuse of Psychotropic Medications for Children in Foster Care

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INTRODUCTION

Youth in foster care represent a vulnerable population. Most have histories of neglect or physical and/or sexual abuse severe enough to require removal from their homes of origin. Foster children, by definition Medicaid eligible, are at greater risk for developing severe emotional and behavioral disturbances and mental illness,[1,2,3] utilize mental health services at higher rates[3,4,5,6] and are more likely to receive psychotropic medications than other Medicaid eligible youth.[7] In December 2011, the Governmental Accountability Office studied the use of psychotropic medication in foster children in five states during 2008 and reported that foster children were prescribed psychotropic medications at higher rates, were more likely to be treated with five or more concurrent psychotropic medication and were more likely to be prescribed higher than recommended doses of psychotropic medications than nonfoster children in Medicaid.[8]

The use of psychotropic medications to treat foster children with emotional and behavioral disturbances presents unique challenges. Unlike mentally ill children from intact families, youth in state care often do not have a consistent interested party to coordinate treatment planning and clinical care or to provide longitudinal oversight of their treatment. The issues of informed consent and oversight of the utilization of psychotropic medications in this population present a particularly vexing problem. Nationally, child welfare agencies have devised several mechanisms to provide consent for treatment of foster children with psychotropic medications.[9]

In Illinois, the Department of Children and Family Services (DCFS) Office of the Guardian is required by state law to provide consent for all youth for whom they have guardianship.[10] DCFS recognized the need to have a clinically-based quality assurance system to safeguard the medical well-being of its wards and contracted with the University of Illinois at Chicago (UIC) Department of Psychiatry in 1993 to establish the Clinical Services in Psychopharmacology (CSP) to provide an independent review of all psychotropic medication consent requests for foster children to ensure the safety, effectiveness, and appropriateness of the planned treatment regimen. The CSP reviews approximately 14,000 psychotropic medication consent requests and reviews approximately 4,000 emergency medication administrations annually. In addition to reviewing medication requests, the CSP:
1) collects data on the utilization of psychotropic medications in foster children statewide;
2) provides consultation on particularly difficult and/or complex cases;
3) compiles psychotropic medication histories for clinical staffings and administrative case reviews;
4) notifies the DCFS Office of the Guardian and Advocacy when local and/or provider patterns warrant further review and possible remediation;
5) disseminates information on new pharmaceutical developments and alerts to prescribing physicians who serve DCFS wards;
6) drafts materials and reviews and comments on DCFS-developed best practice guidelines and policies and procedures governing the management of psychotropic drugs;
7) partners with DCFS to develop programs to provide evidence-based diagnostic assessments and treatment for high risk children; and
8) develops training materials and conducts training for foster parents, other care providers, and DCFS-identified staff in management of psychotropic medications.

I describe the CSP and present data to demonstrate its effectiveness at monitoring clinical trends and adverse effects of psychotropic medications prescribed to foster children and to assess the program's

impact on psychotropic medication prescribing patterns. In Study 1 we looked at potential risk factors for placement disruption for preschool-aged children. In Study 2 we hypothesized that the rate of consent requests for fluoxetine would increase while the rates of other SSRIs would decrease when the CSP endorsed the use of fluoxetine over other SSRIs. In Study 3 we examined the effect of the psychotropic medication review process on the practice of antipsychotic polypharmacy. In Study 4 we hypothesized that atypical antipsychotic medications would cause weight gain and that gender, race and placement would all affect weight gain. In the Discussion, we describe the implications of these findings, describe their impact on policy and program development and discuss their impact on prescriber practice.

METHODS

Physicians or advanced practice nurses wishing to start a foster child on psychotropic medications must submit consent requests to DCFS. Information submitted includes the child's name, DCFS identification number, date of birth, race, height, weight, diagnoses, target symptoms, relevant medical history, current medications, placement, name and dosage of the requested medication(s), clinician's name, and specialty. The requests are forwarded to the CSP where the information is reviewed by a psychiatric nurse and entered into a database. Consent requests are triaged to one of four board-certified child psychiatrist consultants who review every request. The consultant recommends to DCFS that the request be approved; modified (approved at a different dosage, duration, or administration schedule); or denied. The consultant may request additional information in order to make the recommendation. The completed recommendation is then forwarded to DCFS who formally consents to or denies the medication trial.

Other data sources
The CSP has an interagency agreement with the Illinois Department of Healthcare and Family Services, administrator of the state Medicaid program, to obtain data on claims for all psychiatric services including psychiatric hospitalizations and outpatient visits rendered to foster children and claims for all psychotropic medications prescribed to Illinois foster children. The Medicaid payment database includes recipient name and recipient identification number; brand and generic name and National Drug Code; number of psychotropic medications dispensed; prescription date and quantity dispensed; name, ID number, and specialty of the prescriber; diagnosis and ICD – 9 diagnostic code; and admission and discharge dates of psychiatric and medical hospitalizations.

IRB approval was continuously granted for this project from 2005 through 2014 under UIC protocol 2005-0366.

Study 1
Three hundred-nine foster children born between 01/01/2006 and 12/31/2011 and less than six years of age on 12/31/2011 were included in this study. To be included in this study wards had to have received consent for at least one psychotropic medication from DCFS during the study period of 01/01/2006 and 12/31/2011. Fifty-four were excluded from the study because they had been adopted or had returned to their biological families so their placement histories were not available.

Placement disruption, the primary outcome measure (dependent variable), was defined as ≥ 2 placement changes during the study period. Based on a preliminary examination of our data, we identified children on two or more psychotropic medications, children who have been hospitalized, children with history of physical abuse, children with history of sexual abuse, children with psychotic symptoms like hallucinations, children with risky behaviors such as physical and/or verbal aggression, elopement, property destruction, children with mood dysregulation symptoms such as mood instability, children with attention deficit and/or impulsivity, children with depression and/or anxiety, children with disruptive behaviors and last children who had problems with functioning such as school suspension, sleep problems, bedwetting/enuresis as being at high-risk for placement instability.

Backward elimination in multivariate logistic regression modeling was employed to estimate the association between placement disruption and the independent variables. Bayes law was used to calculate the sensitivity and specificity of statistically significant independent variables independently and in combination.

Study 2
Endorsement of fluoxetine
Based on data from clinical trials and post-marketing, the FDA recommended in 2003 that physicians not use paroxetine for children and adolescents due to lack of evidence of efficacy and an increased risk of suicidal behavior.[11] In September 2003 the CSP consultation team began to issue the following statement when a SSRI (except fluoxetine) was requested for the treatment of child depression:

What is the rationale for choosing _____ over fluoxetine? 1) Fluoxetine, but not _____ has been shown to be more effective than placebo in the treatment of pediatric depression, 2) fluoxetine has favorable safety profile with a low likelihood of inducing suicidal ideation, 3) according to the FDA meta-analysis fluoxetine has a low likelihood of treatment emergent agitation and hostility, 4)

the FDA has approved fluoxetine, but not _____ for the treatment of depression in children and adolescents, and 5) fluoxetine is available as a generic.

In March 2004 the FDA issued a public health advisory warning prescribers of possible increases in suicidal behavior associated with the use of selective serotonin reuptake inhibitors in youth.[12]

We used data from the CSP's database to identify all wards with a depressive or mood disorder. Then we determined the monthly number of consent requests for each SSRI antidepressant and grouped them into three categories: fluoxetine, paroxetine, and other SSRIs. This number was divided by the total number of requests for the month to indicate rate of request for SSRIs. Using SPSS 15.0 we performed time-segmented regression analysis to determine the change in rates between August 1998 and June 2008.

The modified regression lines were based on three time points that affected the prescription rate of antidepressants: the FDA paroxetine warning, the beginning of the CSP endorsement of fluoxetine, and the FDA black box warning. Best fit regression models were determined by backward elimination, reducing a model until all factors (Constant – intercept, Time – slope, Paroxetine Intervention – intercept, Time after Paroxetine Intervention – slope, CSP Intervention – intercept, Time after CSP Intervention – slope, Black Box Intervention – intercept, Time after Black Box Intervention – slope, and a seasonal variable) were significant at $p<.05$. We also performed time-segmented regression on the rate of requests for stimulants in this population to determine if the CSP intervention had a targeted effect on SSRIs rather than a global effect.

Study 3

In FY 2005 we undertook an effort to decrease the use of antipsychotic polypharmacy (the concurrent use of two or more antipsychotics). A policy was implemented to require at least two adequate monotherapy trials, as defined by adequate dosage of the medication and duration of the trial, and one typical neuroleptic trial before polypharmacy would be considered. In addition, the use of antipsychotic medications to treat insomnia was disallowed. Low dose ($\leq$ 100 mg) bedtime trials of quetiapine, a second generation antipsychotic medication, was approved for only limited periods of time (3 – 10 days). The rate of antipsychotic polypharmacy was defined as the percentage of children on one or more antipsychotic medications that were on two or more. Rates of antipsychotic medications were compared for the 0 – 6, 7 – 11, and 13 – 17 year old age groups and for all children 0 – 17 years between FY 2005 and FY 2012.

Study 4

Subjects' medication payment histories were matched by recipient identification number (RIN) to consent information in the CSP database from July 1998 to June 2007, and subsequently de-identified. Records were excluded if the child was 18 years of age or older at the date of the prescription, if the RIN was missing, or if the RIN did not match a child the CSP database.

A medication trial was defined as starting on the date the prescription was first filled and ending 30 days after the last prescription refill. In order to be included in the sample the child must have, at some point, received a psychotropic medication. Patients who had an antipsychotic trial within the 90 days prior to the first antipsychotic trial in the Medicaid claims database were excluded from the study. To be considered a valid trial with continuous use of the medication, there could be no gaps greater than 60 days between refills of the same medication and there must have been at least three recorded weights during the trial. During the course of the study, if a patient had multiple trials of antipsychotic treatment, only the first valid trial was used in the analysis.

In addition to absolute weight change, we studied age- and gender- corrected changes in body weight (z-score). Weight measurements were converted into z-scores using the gender specific Center for Disease Control growth norms.[13] Weight values with z-scores below -3 and above +3, were evaluated in relationship to weight curves for the specific subject, and all were excluded as errors.

As most subjects included in the final analysis were either Black or White, we excluded subjects in other race categories.

Data was analyzed using SPSS software. Chi-square tests were performed to look for significant differences between placement, age, gender, and race in subjects taking different SGAs. Placement, either foster care or in residential treatment, was assigned based on the placement for which the subject had the most data points in the CSP database. For the purpose of this analysis, hospitalization was not considered a placement.

Baseline weight was defined as the weight obtained immediately preceding, less than 90 days prior to, the medication trial. The maximum weight recorded during the drug trial represented the peak weight gain.

We analyzed age in 3 categories: preschool (0-6 years), prepubertal (7-12 years), and pubertal (13-17 years). Race was split into 6 categories: Black, White, Hispanic, Native American, Asian or Pacific Islander, and unknown. Antipsychotics studied included ziprasidone, quetiapine, olanzapine, risperidone, and aripiprazole. Clozapine had insufficient data for analysis.

In order to evaluate weight gain by drug, we used a paired t-test to compare baseline weight with peak weight. To rank the medications, we did pair-wise comparison of SGAs adjusted by demographic variables of age, gender, race, and placement. We determined risk factors for weight gain by performing an ANCOVA analysis with age, race, gender, placement, and SGA as factors and baseline weight as a covariate.

RESULTS

Study 1

The final study sample consisted of 255 children; 72% were male, 47% were white, 46% were African American and 7% were other (Hispanic, biracial, unknown). Fifty-one percent (n = 37) of females experienced placement disruption as compared to 46% (n = 85) of males. Approximately 50% of African Americans experienced placement disruption as compared to 48% (n = 56) of Caucasian children and 33% (n = 6) of Other.

Statistically significant risk factors of placement disruption were: polypharmacy, psychiatric hospitalization, physical and sexual abuse. Table 1 depicts the respective β estimates, odds ratios and their p-values of the four risk factors that were identified in this research study.

Risk factor	β estimate	Odds ratio estimate OR (95% confidence interval)	*p*-value
Intercept (β_0)	-1.35		<0.0001
Polypharmacy	0.66	1.93 (1.1 - 3.5)	0.027
Psychiatric Hospitalization	0.92	2.5 (1.2 - 5.3)	0.016
Physical Abuse	0.99	2.7 (1.3 - 5.3)	0.004
Sexual Abuse	0.63	1.87 (1 - 3.5)	0.05

Table 1: Risk factors for placement disruption

The best combination of risk factors identified in this study for the purpose of a brief screening measure to identify children at risk for placement disruption measure was polypharmacy combined with psychiatric hospitalization. The sensitivity and specificity of this combination was 50.7% and 70.2% respectively.

Study 2

We found that fluoxetine consent requests significantly decreased before the CSP statement but increased significantly afterward. The fluoxetine request rate continued to rise after the FDA black box warning. In contrast, other SSRI rates rose significantly before the intervention and fell steadily afterward Requests for paroxetine declined from the start of the study period and then dropped dramatically after the paroxetine warning.

After the CSP intervention the decline accelerated until the proportion of requests neared zero. Adjusted R^2 for fluoxetine, paroxetine, and other SSRIs were 0.79, 0.92, and 0.79, demonstrating that the regression lines are a very good fit to the data (see Figure 1).
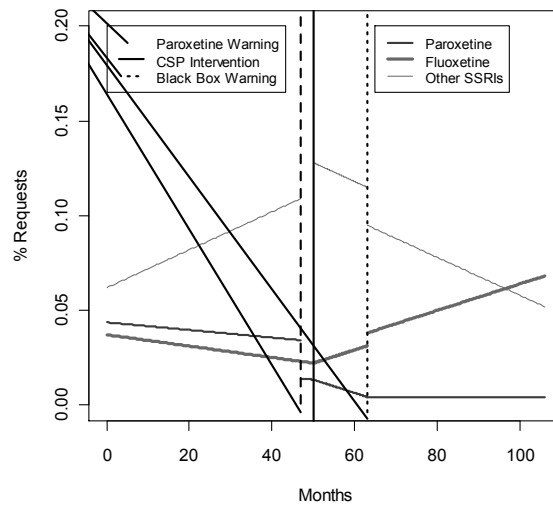
Figure 1: The reduced regression model of rate of change in the request of fluoxetine, paroxetine, and other SSRIs.

Study 3
As a result in the change in policy, there was a 48% decrease in the rate of antipsychotic polypharmacy in all ages from FY 2005 to FY 2012. Particularly large decreases were seen in the 0 − 11 year age groups [45 (4.7%) to 9 (1.1%)], a 77% decline (see Table 2).

	FY 2005		FY 2012	
Age	Any antipsychotic	$\geq$ 2 antipsychotics	Any antipsychotic	$\geq$ 2 antipsychotics
0 - 6	94	2 (2.1)	49	0 (0)
7 - 11	866	43 (5.0)	735	9 (1.2)
13 - 17	1476	164 (11.1)	1239	83 (6.7)
Total	2,436	209 (8.6)	2,023	92 (4.5)

Table 2: Rate of antipsychotic polypharmacy in FY 2005 and FY 2012

Study 4
Using a paired t-test, we compared the baseline weight and peak weight by drug. We found that all 5 antipsychotics caused significant weight gain in both weight and z-score (all $p < 0.0002$). Weight gain in both raw weight and z-score has the same pattern, with olanzapine causing the most weight gain, followed by risperidone, quetiapine, aripiprazole, and ziprasidone. Using a pair-wise comparison of change in z-score, olanzapine caused the most weight gain (all $p < 0.05$) followed by risperidone (all $p<.05$). There was no significant difference in weight gain between quetiapine, aripiprazole and ziprasidone.

In order to determine risk factors for weight gain we performed an ANCOVA analysis with change in z-score as the outcome variable. Due to baseline significant differences in weight, baseline z-score was used as a covariate, and age, gender, race, and placement were used as factors. When baseline weight, demographics, and prescribed antipsychotic were controlled for, gender and placement remained as significant factors. Females gained more weight than males (p = 0.003), while youth in residential settings gained more than youth in foster care settings (p < 0.0001).

Medication (n)	Weight lb (S.D.)	D weight (S.E.)	Z-score (S.D.)	D Z-score (S.E.)
Risperidone (654)				
Baseline	92.5 (43.0)	25.1 (1.02)[1]	0.32 (1.09)	0.64 (0.03)[1]
Peak	117.6 (52.4)		0.96 (1.07)	
Olanzapine (168)				
Baseline	95.9 (40.4)	29.8 (2.1)[1]	0.27 (1.02)	0.88 (0.07)[1]
Peak	125.7 (49.4)		1.15 (0.85)	
Quetiapine (282)				
Baseline	119.1 (47.5)	21.4 (1.49)[1]	0.73 (1.06)	0.46 (0.04)[1]
Peak	140.5 (51.9)		1.19 (1.04)	
Aripiprazole (158)				
Baseline	123.3 (48.2)	19.5 (1.77)[1]	0.83 (1.21)	0.42 (0.06)[1]
Peak	142.8 (54.0)		1.25 (1.02)	
Ziprasidone (125)				
Baseline	136.6 (51.8)	16.81 (2.04)[1]	1.10 (1.09)	0.23 (0.06)[2]
Peak	153.4 (53.7)		1.33 (1.05)	

[1] – p < 0.0001
[2] – p = 0.0002

Table 3: Peak weight gain as compared to baseline weight gain

DISCUSSION

We have shown that a prospective psychotropic medication consent and oversight process can result in higher quality and potentially more cost effective care. Based on the findings described above, DCFS has:

- designed and implemented a program that provides specialty evaluations of and evidence-based psychosocial treatments for preschool-aged children in an effort to decrease placement disruption and decrease reliance on psychotropic medications in this age-group.
- increased adherence to evidence-based prescribing for the treatment of pediatric depression. While we do not have outcome data to assess the effectiveness of this strategy, this has resulted in increased use of off-patent medications and decreased the use of non-FDA approved brand name medications. Presumably this has resulted in a cost savings. Using data now available, we will be able to examine this going forward.

- substantially decreased the concurrent prescription of two or more antipsychotic medications. While we have not analyzed the health impact of the use of antipsychotic polypharmacy, we anticipate that the rate of obesity and of the metabolic syndrome and Type II diabetes will decrease. Additionally, it is likely that the decreased use of antipsychotic medications has resulted in a substantial cost savings. Again, using data now available, we will be able to examine these going forward.
- improved the monitoring of adverse effects of psychotropic medications, for example, documenting the extent of weight gain that accompanies the use of second generation antipsychotics. DCFS has written and implemented a policy linking consent for second generation antipsychotics to effective medication monitoring strategies.

Though we do not have data supporting these contentions, anecdotal evidence suggests that the prospective psychotropic medication consent and oversight has:
- improved continuity of care for these high risk youth, preventing the use of medications that have proved ineffective in previous trials or that have resulted in significant adverse effects.
- improved safety of pharmacotherapy through the prevention of potentially serious, even fatal, drug interactions.

In 2008, Congress passed and the president signed into law Public Law 110-351, ''Fostering Connections to Success and Increasing Adoptions Act of 2008''.[14] The law requires that state Medicaid agencies and state child welfare agencies provide ongoing coordination of medical and psychiatric services and monitor utilization of medications, including psychotropic medications. This law was amended in 2011 by P.L. 112-34, the "Child and Family Services Improvement and Innovation Act" to require states to outline protocols for the appropriate use and monitoring of psychotropic medications.[15] The Illinois model of providing consent for psychotropic medications for foster children and monitoring the use of these medications is widely regarded as a pioneer and leader in this arena and has received considerable attention. The lessons learned in the development and implementation of the Illinois model for providing consent for psychotropic medications and overseeing the utilization of these medications in foster children can provide valuable guidance to other states as they move to develop similar programs.

As demonstrated by the Illinois experience, a well-designed and implemented medication consent and oversight program that provides effective longitudinal oversight of a youth's care and monitoring of prescribing patterns can improve the continuity and quality and increase the cost-effectiveness of care provided to foster children. Anticipated benefits of the consultation and educational services for foster parents, childcare workers, and caseworkers include increased placement stability and reduced need for psychiatric hospitalization.

DCFS Centralized Psychotropic Medication Consent Line and the Clinical Services in Psychopharmacology Program for their role in collecting data.

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