

Psychotropic Medication Management for Youth in State Care: Consent, Oversight, and Policy Considerations

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The use of psychotropic medications in youth with emotional disturbances in state custody is increasing and presents unique challenges concerning consent and oversight. We examine various means that state child welfare agencies use to provide consent for and oversight of psychotropic medications for children in state custody and describe benefits of a consent process that provides for expert consultation to the child welfare agency and prescribing clinicians, case-specific and systemic oversight of psychotropic medication use, and education for stakeholders.

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With few exceptions, youth in foster care have been physically or sexually abused, neglected, or both. A significant body of literature shows that children in foster care are at higher risk for developing emotional and behavioral disturbances and mental illness (McIntyre & Keesler, 1986; Trupin, Tarico, Low, Jemelka, & McClellan, 1993; Harman, Childs, & Kelleher, 2000; dosReis, Zito, Safer, & Soeken, 2001; Burns et al., 2004) than youth from comparable backgrounds. Reflective of their high rates of mental illness and emotional disturbances, children and adolescents in substitute care (by definition eligible for Medicaid benefits) use mental health services at higher rates than other Medicaid-eligible youth (Halfon, Berkowitz, & Klee, 1992; Harman et al., 2000; dos Reis et al., 2001). Furthermore, children and adolescents in substitute care are more likely to receive psychotropic medications than other Medicaid eligible youth (dos Reis et al., 2001; Raghavan, Zima, Anderson, Leibowitz, Schuster, & Landsverk, 2005). Indeed, up to 13.5% of children and adolescents in foster care are prescribed psychotropic medications (Zima, Bussing, Crecelius, Kaufman, & Belin, 1999; Raghavan et al., 2005). Level of care predicts the use of psychotropic medications. Youth in group homes are significantly more likely to be prescribed psychotropic medications than those in therapeutic foster care (Breland-Noble, Elbogen, Farmer, Dubs, Wagner, & Burns, 2004).

The use of psychotropic medications for the treatment of youth with severe emotional and behavioral disturbances has increased dramatically over recent years. Zito et al. (2003) reported a two- to threefold increase in the prevalence of psychotropic medications between 1987 and 1996, with particularly rapid growth in prescribing α -agonists such as clonidine and guanfacine, antipsychotic medications, and anticonvulsant medications prescribed as mood stabilizers. They concluded that the rate of prescribing psy-

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chotropic medications for children and adolescents is approaching that seen in the adult population.

The increasing use of psychotropic medications is paralleled by a two-point-five- to eight-fold increase in the rate of polypharmacy, the coadministration of two or more psychotropic medications, between the late 1980s and the late 1990s (Olfson, Marcus, Weissman, & Jensen, 2002; Safer, Zito, & dos Reis, 2003; Bhatara, Feil, Hoagwood, Vitiello, & Zima, 2004). Anderson and colleagues found that the rate of polypharmacy in children in foster care in Illinois increased between the mid 1990s and the early 2000s (Anderson, Naylor, Kruesi, & Stoewe, 2002). Higher rates were reported for children and adolescents treated in psychiatric hospitals and residential centers and for youth in foster care (Safer et al., 2003; Bhatara et al., 2004). Combining psychostimulants and antidepressants is particularly common (Olfson et al., 2002; Bhatara et al., 2004).

Research supporting the practice of polypharmacy in the pediatric population is sparse. While recent reports have been published in the child and adolescent psychiatric literature supporting specific psychotropic medication combinations (Delbello, Schwiers, Rosenberg, & Strakowski, 2002; Aman, Binder, & Turgay, 2004; Pavuluri, Henry, Carbray, Sampson, Naylor, & Janicak, 2006), most of these are case series or open-label trials. Furthermore, studies examining the efficacy of polypharmacy are limited to the use of two psychotropic agents. No research supports the safety and efficacy of the use of three or more psychotropic medications concurrently. Safer et al. (2003) and Bhatara et al. (2004) conclude that the available safety and efficacy data on polypharmacy are inadequate to inform clinical practice.

Recently advocacy groups and newspaper editorials have raised concern about the use of "off-label" psychotropic medications in children and adolescents. The label information—in the package insert, in the Physicians Desk Reference (PDR, 2006), and in any advertising—can indicate a drug's use only in approved

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doses, in routes of administration, and in specific populations. A review of the PDR (2006) shows that approximately 45% of medications used for the treatment of emotional or behavioral disturbances in children or adolescents are off-label, having no approved use for patients under age 18. Only 31% of psychotropic medications are approved for the treatment of a psychiatric disorder in this age group. Some medications, such as divalproex sodium and clonidine, are approved for the treatment of specific medical illnesses in patients less than 18 years of age but not for the treatment of psychiatric disorders. The off-label use of medications in the pediatric population is not unique to psychotropic medications (Blumer, 1999). Significantly, off-label use of drugs by prescribers is not only legal but may represent the standard of care. Prescribers have the responsibility, however, to be well informed about the product, to base its off-label use on firm scientific rationale and sound medical evidence, and to maintain records of the product's use and effects.

In 1999, Jensen and colleagues commented on the paucity of research on the safety and efficacy of the off-label use of psychotropic medications in children and adolescents (Jensen, Bhatara, Vitiello, Hoagwood, Feil, & Burke, 1999). While the amount of research on the use of psychotropic medications in children and adolescents has increased, the Code of Federal Regulations (USDHHS, 2001, 2003) identifies children in state care as a vulnerable population in need of special protection, prohibiting the involvement of children in state care in research involving greater than minimal risk. Consequently, clinicians are forced to extrapolate data from findings in the adult psychiatric literature or in children with mental illness who are not in state care. Caution must be exercised in generalizing findings from these populations to children in foster care who have many unique risk factors, including emotional and physical sequelae of abuse and neglect, disrupted attachment relationships, and placement disruptions, which can all have an effect on clinical presentation.

Other factors have raised the visibility of the use of psychotropic medications in children and adolescents. Recently, the

FDA has raised questions about the safety and efficacy of the selective serotonin reuptake inhibitors (SSRIs), such as fluoxetine, sertraline, and paroxetine (USFDA, 2004), and the safety of central nervous stimulants, such as methylphenidate (Phelan, 2005), in children and adolescents. Additionally, a recent study found that the use of antipsychotic medications in children and adolescents increased dramatically between 1993 and 2002 (Olfson, Blanco, Liu, Moreno, & Laje, 2006), mostly due to the availability of the second-generation antipsychotics (risperidone, olanzapine, quetiapine, clozapine, ziprasidone, aripiprazole), which have fewer short-term adverse effects, including decreased sedation, decreased extrapyramidal and anticholinergic side effects, and a lower risk of developing tardive dyskinesia (Correll, Leucht, & Kane, 2004) than first-generation antipsychotics. There is concern about the safety of the second-generation antipsychotics, however, as their use has been linked to obesity, the development of Type II diabetes mellitus, and hyperlipidemia (Stigler, Potenza, Posey, & McDougle, 2004). More recently, the death of a 4-year-old girl—diagnosed with ADHD and bipolar disorder at age 2 and treated with clonidine, divalproex sodium, and quetiapine—raised serious questions about the appropriateness and safety of these medications in children (AP, 2006). Safety concerns in conjunction with concerns about the increasing use of psychotropic medications in children and adolescents, the off-label use of psychotropic medications in this age group, and the paucity of research to support many of the psychotropic medication practices used in the pediatric population have resulted in increased scrutiny of the practice of prescribing psychotropic medications to youngsters.

The use of psychotropic medications by children in state care presents unique challenges, particularly regarding issues of consent for and the oversight of psychotropic medications. 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, to provide informed consent for their treatment, or to provide longitudinal oversight of their treatment.

We undertook this project to examine the range of approaches that state agencies have implemented to obtain consent for and provide oversight of the use of psychotropic medication. We also describe benefits of a consent process that provides expert consultation to the child welfare agency and prescribing clinicians, case-specific and systemic oversight of psychotropic medication use, and education for stakeholders.

Method

A brief open-ended questionnaire was sent via e-mail to the child welfare agency in each of the 50 states, requesting a response from the official responsible for mental health or medical policies or services. The project's nurses conducted phone interviews with many respondents to obtain additional information or clarification and to initiate contact with agencies that had not returned the questionnaire. The questionnaire and interviews covered current policies and procedures pertaining to consent and oversight for psychotropic medications; whether these policies and procedures are administered at the state or county level; requirements for review of medication requests or consultation by a licensed health care professional; and use of a formulary (i.e., an approved list of medications).

For the purposes of this project, the consent procedures described here are for children and adolescents for whom parental rights were terminated. Data relating to psychotropic medication consent and oversight policies and practices were tabulated and specific examples were given to highlight various aspects of the consent and oversight procedure.

Results

The project obtained data from 34 states, with completed questionnaires or interviews obtained from 29 states and information from the child welfare agencies' websites from five. Respondents included mental or behavioral health program directors and medical

TABLE 1

Summary of psychotropic medication consent procedure by state¹

STATE	SPECIFIC POLICY EXISTS FOR CONSENT - PERSON AUTHORIZED TO GIVE CONSENT ³	POLICY EXISTS FOR OVERSIGHT OF CONSENT FOR PSYCHOTROPIC MEDS	POLICY IMPLEMENTED AT STATE OR COUNTY LEVEL	MEDICATION REQUEST REVIEW OR CONSULTATION BY LICENSED HEALTH CARE PROFESSIONAL	USE OF FORMULARY ³
Alabama	Yes - LG, P	Yes	State	No	Unk
Alaska ²	Yes - W	Unk	Unk	Yes	Unk
Arizona	Yes - CO, LG, P	Yes	State	No	Yes
Arkansas	Yes - W	No	State	No	No
California	Yes - CO	Unk	Unk	Unk	Unk
Connecticut	Yes - LG, P	Yes	State	In some cases	Yes
Florida	Yes - CO	Yes	State	Unk	Unk
Georgia	In RTC - W	In some cases	County	No	Unk
Hawaii	In RTC - LG	No	State	Available	No
Illinois	Yes - LG	Yes	State	Yes	MA
Iowa	No	No	State	No	MA
Kansas	Yes - CA, P	No	State	No	No
Kentucky	Yes - P, W	No	Unk	Available	Unk
Louisiana	No	No	NA	NA	MA
Maryland	Yes - W	Yes	County	No	No
Massachusetts	Yes (antipsychotics) - CO	Unk	Unk	No	No
Minnesota ²	Yes - CO	Unk	Unk	Unk	Unk
Missouri	No	No	NA	NA	No
Montana	No	No	NA	NA	MA
Nebraska	Yes - W	Yes	State	Available	No
New Jersey	In RTC - LG, P	No	State	No	Unk
North Carolina	No	No	County	No	No
North Dakota ²	In RTC - LG	Unk	Unk	Unk	Unk
Ohio	No	No	County	No	No
Oklahoma	No	No	State	No	Yes
Oregon ²	No	No	NA	No	Unk
Pennsylvania	Yes - CO	Yes	State	No	MA
South Dakota	No	No	State	No	No
Tennessee	Yes - RN	Yes	State	Yes	MA
Texas	Yes - CA	Yes	State	No	MA
Vermont	Yes - W	No	Unk	No	No
Virginia	Unk	Unk	Local office	Unk	Unk
Washington ²	Yes - W	No	State	No	MA
West Virginia	In RTC - Unk	No	State	No	MA
Wyoming	No	No	State	No	Unk

¹ Information not available on Colorado, Delaware, District of Columbia, Idaho, Indiana, Maine, Michigan, Mississippi, Nevada, New Hampshire, New Mexico, Rhode Island, South Carolina, Utah, and Wisconsin.

² Information obtained exclusively from website.

³ Key: NA=Not Applicable; CA=Custodial Agency; CO=Court Ordered; FP=Foster Parent; LG=Legal Guardian or Designee; MA=Medicaid; P=Parent; RN=Dept. Nurse; Unk=Unknown; W=Worker

directors or their designees; senior managers of other direct services, such as residential and foster care; and officials with responsibility for policy development or quality assurance programs.

Consent

State and county child welfare agencies have established a variety of means of providing consent for prescribing psychotropic medications for youth in state custody (Table 1). The most common method is for the legal guardians or parents to give consent ($n = 8$), followed by caseworkers ($n = 7$), and court order ($n = 6$). Other states have designated specific officials or created specific offices within the child welfare agency to provide consent for psychotropic medications. In Illinois, the Department of Guardian and Advocacy was established to provide consent for medical care, including treatment with psychotropic medications. In Connecticut, Program Supervisors provide consent, whereas 12 regional health nurses have this responsibility in Tennessee.

Court consent is required prior to administering psychotropic medications to children in custody in six states, though in some instances only if the biological parents cannot be located. Judicial consent must be obtained before an antipsychotic can be prescribed in residential treatment centers in Massachusetts, though court consent is not required for other psychotropic medications.

Consultation

Seven state child welfare agencies use mental health and psychiatric consultation as part of the consent process. In Illinois, DCFS contracts with the University of Illinois at Chicago to provide an independent review of all psychotropic medication requests by a board certified child and adolescent psychiatrist for youth in state care. In addition, consultation is available to case managers to review the appropriateness of a child's diagnosis and medication regimen and to treat clinicians for particularly complex cases.

Tennessee requires that all psychotropic medication requests for youth under age 5 be approved by a psychiatrist in the Department

of Children's Services central office and that all consent requests for youth aged 6–10 be reviewed by the nurse practitioner and the psychologist or psychiatrist in the central office before the treating clinician can start the medication. Additional consultation to clarify the appropriateness of a consent request can be obtained from one of three Centers of Excellence for Children in Custody located at the University of Tennessee Memphis, Vanderbilt University, and East Tennessee State University.

In Connecticut, Program Supervisors must consult with medical specialists in the department at one of three levels prior to consenting to administering psychotropic medications. A Level I consultation with a Regional Resource Group (RRG) Nurse is necessary for psychotropic medication requests for children under 5 years and for any child on more than two psychotropic medications. A Level II consultation by the RRG Nurse and the Director of Psychiatry is required for any child with complex medical needs, the use of more than four psychotropic medications, and the use of nonformulary medications. A Level III consultation by the RRG Nurse, the Department of Children and Families (DCF) Physician or Director of Psychiatry, and the Department Psychiatric Review Board is mandated for children with chronic or recurrent psychiatric disorders that include a threat of harm to self or others or with grave disability unresponsive to multiple psychiatric interventions and whose treatment may require the use of nonstandard treatment modalities.

Oversight

Most states provide informal case level oversight of psychotropic medication usage through ongoing child and family treatment planning conferences. The caseworker from the child welfare agency, the child's attorney, the foster parent or representative from the child's current placement, the advocacy programs representing the child, the program manager for the behavioral health section of the child welfare agency, the mental health clinicians, and other stakeholders provide some degree of oversight of the treatment plan and the use of psychotropic medications.

Several states have developed specific programs to monitor the use of psychotropic medications ($n = 11$). State oversight can be case-specific, for example, overseeing the appropriateness of a particular youth's pharmacological regimen. The Florida Department of Children and Families provides an update to the court detailing the child's medical and behavioral status as part of the regular social services report for judicial review hearings. The update reviews the child's psychotropic medication management and all pertinent medical records that have been generated since the last review. The court may order the child welfare agency to obtain a second opinion addressing the safety and appropriateness of the continued use of psychotropic medications or order additional consultation with the MedConsult line at the University of Florida.

Some state agencies have devised system-wide strategies to oversee the use of psychotropic medications. Some states, such as Arizona and Texas, have devised best practice protocols to enhance the quality of psychotropic pharmacotherapy. These guidelines serve to establish minimal standards against which the quality of clinical care can be measured. In Arizona, the Division of Behavior Health Services has developed a Practice Improvement Protocol entitled *The Use of Psychotropic Medication in Children and Adolescents* that offers guidelines for prescribing psychotropic medications to children. Regional Behavioral Health Authorities are charged with the responsibility of monitoring prescribing psychotropic medications by reviewing utilization data, prescribing patterns, and peer review to identify unsafe or unsound prescribing practices and to implement improvement actions. The Texas Department of Family and Protective Services (DFPS), in conjunction with a panel of child and adolescent psychiatrists, psychologists, and other mental health professionals, recently developed best practice guidelines, *Psychotropic Medication Utilization Parameters for Foster Children*.

Three states, Connecticut, Illinois, and Tennessee, have established databases to monitor the use of psychotropic medications in children and adolescents in state custody. These databases

allow the state's child welfare agency to track informed consent for psychotropic medications documentation and to review prescribing patterns by placement, discipline, region, or individual clinician. Tennessee's database is maintained on the Department of Children's Services (DCS) intranet while University of Illinois-Chicago (UIC) maintains the consent database for the Illinois DCFS and has the capacity to cross-check consents with payment data from the Illinois Department of Public Aid. This enables the Illinois DCFS to document that medications have actually been dispensed and to monitor practitioner and caregiver compliance with the consent procedure.

State child welfare agencies often partner with the sister state agency that manages the state Medicaid program to provide oversight of use of psychotropic medications for children in foster care. In Pennsylvania, the Bureau of Data and Claims Management monitors the use of psychotropic medications for youth in county-administered, state-supervised, substitute care. In North Carolina, a pharmacist or physician must review the psychotropic medication regimen of any child on Medicaid at least every six months. The Texas Health and Human Services Commission, which manages the Texas Medicaid program, is designing a physician-directed medical review process to evaluate psychotropic medication use in children under DFPS custody.

Pro Re Nata Medications

Pro re nata (PRN) medications are standing orders that allow caregivers in group home, residential, or hospital settings to administer a psychotropic medication for the emergency management of aggression, psychotic agitation, insomnia, and other troublesome symptoms without a physician assessment or specific approval. While the prescribing clinician typically sets parameters for the use of these medications, the decision to medicate is placed in the hands of the milieu staff, typically a nurse. While clearly not the intent, PRN medications may encourage reliance on the use of medications to manage disruptive behaviors rather than psychosocial or

behavioral interventions. Illinois specifically prohibits the use of standing PRN medication orders, though the patient's physician can prescribe emergency medications without prior consent to manage an acute crisis after an appropriate assessment. All emergency medications are subsequently reviewed by UIC. Excessive or inappropriate use of emergency medications prompts an inquiry by the DCFS Department of Guardian and Advocacy or the Office of the Public Guardian into the child's treatment plan, the effectiveness of the placement, or the clinician's use of emergency medications.

In Tennessee prescribing PRN medications for youth in state care requires a separate consent that is reviewed by the regional health unit nurse and then sent to the DCS central office for approval by the psychologist or psychiatrist. Consent for PRN medications is time-limited. In Connecticut, standing PRN orders for psychotropic medications requires a Level I consultation with a Regional Resource Group (RRG) Nurse. In Alabama, administering PRN psychotropic medications two or more times weekly for three weeks will trigger a comprehensive case review of a child's service and behavior management plans.

Discussion

As legal guardians, state child welfare agencies are charged with the safety and well-being of children and adolescents in their care. Guardianship responsibilities include providing consent for treatment and providing longitudinal oversight of treatment plans. State child welfare agencies have devised various means of meeting these responsibilities, ranging from authorizing legal guardians or caseworkers to provide consent to having a centralized consent program for psychotropic medications. States with centralized consent programs often combine them with consultative programs and systems to monitor the use of psychotropic medications in this vulnerable population.

A psychotropic medication consent program that provides effective longitudinal oversight of a youth's care, monitoring of prescribing patterns, and consultative and educational services for foster

parents, childcare workers, and caseworkers has several potential benefits. Improved oversight of pharmacotherapy may result in enhanced continuity of care, increased placement stability, reduced need for psychiatric hospitalization, and decreased incidence of adverse drug reactions and dangerous drug-drug interactions.

Despite the potential benefits of such a consent and oversight program, however, implementation could face barriers. Adequate resources are needed to support the consent and oversight process. For example, practice guidelines, formularies, and information on relevant policies and procedures must be made available to clinicians, foster parents, hospitals, mental health clinics, and residential and group home providers. Prescribing clinicians may view a centralized consent and oversight system as limiting their autonomy and creativity or as second-guessing their clinical judgment. Furthermore, they may disagree with the recommendations of the consultant for the consent process or may lack confidence in the guidelines on which the oversight process is based (Mellman, Miller, Weissman, Crismon, Essock, & Marder, 2001). Foster parents, especially relatives of the child or adolescent for whom psychotropic medications are being recommended, may believe they are empowered to provide consent for treatment with psychotropic medications and may not inform the treating physician about the nature of the guardianship relationship. Caseworkers, clinicians, foster parents, and other care providers may perceive this as yet another impediment to providing the kind of care and service that brought them to the child welfare population in the first place and may not comply with the consent process.

An effective centralized psychotropic medication consent and oversight process also requires appropriate enabling legislation to establish who is capable of and responsible for consenting for treatment for youth in state care; an invested child welfare agency willing to assume authority; rules, policies, and procedures detailing the mechanism by which consent is granted; and a database to track the use of psychotropic medications in this patient population. In 2005 the American Academy of Child and Adolescent Psychiatry approved a document entitled *Oversight of Psychotropic*

Medication Use for Children in State Custody: A Best Principles Guideline (AACAP, 2005). The position statement lists minimal, recommended, and ideal guidelines for obtaining informed consent and assent. Among other things, it recommends expert psychiatric consultation to the consent process; development of a mechanism for overseeing psychotropic medication use by youth in state care; and the design of a centralized website to provide ready access for clinicians, foster parents, and other caregivers to pertinent policies and procedures governing psychotropic medication management, psychoeducational materials about psychotropic medications, consent forms, and adverse effect rating forms.

Child welfare agencies might find value in partnering with academic child psychiatry programs to design and implement programs to provide consultation to the consent procedure and to monitor statewide psychotropic medication prescription patterns. Academic child psychiatry programs may be in a better position than private clinicians to use evidence-based practices in reviewing consent requests and are more likely to have the resources and expertise necessary to design and maintain computerized databases, to monitor psychotropic medication use, and to design quality improvement programs. In order to be fully credible with community-based clinicians treating this population, academic programs that provide a centralized consent and monitoring service should also provide direct clinical care for children in state custody who have severe emotional, behavioral, and psychiatric disorders such as the specialized program we developed at UIC (Naylor, Anderson, & Morris, 2003).

Funding such a program can be challenging. Matching Title IV-E monies may be available through the state agency's Title IV-E training program if outlined and justified in the agency's training plan (USDHHS, 1998). Title IV-E regulations allow for up to 75% matching funds for costs associated with training personnel employed or preparing for employment by the state or local agency administering the Title IV-E program. Title IV-E also covers short-term training expenses for current and prospective foster or adoptive parents and staff members of licensed child care institutions

providing care to foster and adopted children receiving Title IV-E assistance. According to Title IV-E regulations, training topics must be related to the placement of children in out-of-home care. Child welfare agencies clearly have an advantage by partnering with state universities to design and implement these training programs, as the 75% matching rate is available only for public universities compared to the 50% matching rate available for private universities.

Conclusion

Due to their increasing utilization, the prescription of psychotropic medications in children and adolescents in foster care has come under increasing scrutiny. The use of psychotropic medications by children in state care presents unique challenges, particularly concerning issues of consent for and the oversight of psychotropic medications. State and county child welfare agencies have established a variety of means of providing consent for prescribing psychotropic medications for youth in state custody, ranging from authorizing legal guardians or caseworkers to provide consent to having a centralized consent program for psychotropic medications. States with centralized consent programs often combine them with consultative programs and systems to monitor the use of psychotropic medications in this vulnerable population. A psychotropic medication consent program that provides effective longitudinal oversight of a youth's care, monitoring of prescribing patterns, and consultative and educational services for foster parents, childcare workers, and caseworkers has several potential benefits. Child welfare agencies might find value in partnering with academic child psychiatry programs to design and implement programs to provide consultation to the consent procedure and to monitor statewide psychotropic medication prescription patterns. Academic child psychiatry programs may be in a better position than private clinicians to use evidence-based practices in reviewing consent requests and are more likely to have the resources and expertise necessary to design and maintain computerized databases, to

monitor psychotropic medication use, and to design quality improvement programs. Funding such a program can be challenging. Matching Title IV-E monies may be available through the state agency's Title IV-E training program if outlined and justified in the agency's training plan.

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