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A REPORT ON FAMILY EXPERIENCES WITH THE USE AND MONITORING OF ANTIPSYCHOTIC MEDICATIONS FOR THEIR CHILDREN

Spring 2018

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DEDICATION

To the children, youth and families who struggle with mental health challenges and the service providers who strive to help them.

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ABOUT FREDLA

The Family-Run Executive Director Leadership Association (FREDLA) is a national network of family-run organizations across the United States. FREDLA works to build leadership and organizational capacity of family-run organizations. FREDLA grew out of the family movement and has a vested interest in ensuring that the family-run organizations are strong, and every family member's voice is heard throughout the system.

FREDLA has grown to become a respected source of information and technical assistance to states, communities, and family-run organizations. FREDLA is a partner in two national technical assistance centers: The National Training and Technical Assistance Center for Children's Behavioral Health facilitated by the University of Maryland School of Social Work and funded through the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Center for Applied Research Technical Assistance Center for Health Transitions and Project Aware, also funded by SAMHSA.

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EXECUTIVE SUMMARY

The following report was prepared for the expert panel convened by Substance Abuse and Mental Health Services (SAMHSA) to develop a SAMHSA Guidance Document for Effective Implementation of Antipsychotic Medication Safety Guidelines in Children and Adolescents. The Family-Run Executive Director Leadership Association (FREDLA) conducted four focus groups of family leaders and caregivers to obtain family input for the expert panel. Twenty-three staff from family-run organizations that provide peer support to families with children who have mental and behavioral health challenges and five caregivers participated in the focus groups in February and March 2018. FREDLA staff obtained informed consent from participants and used a standard protocol to solicit information about families' experiences with the use and monitoring of second generation antipsychotic medications (SGAs). Focus group participants represented families in 18 states. Focus group discussions were audiotaped and transcribed. Transcripts were coded and subjected the thematic analysis. The report summarizes the key themes, utilizing quotes from families who participated in the focus groups and makes recommendations for improving the use and monitoring of antipsychotic medications from the family point-of-view.

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INTRODUCTION

Antipsychotic medications prescribed for the treatment for children, adolescents, and young adults with mental and behavioral health challenges have grown in usage. Through the mid-2000s, there was a dramatic increase in the numbers of children less than 6 years old to young adults in the United States who were prescribed antipsychotic medications (Correll et al., 2009; Olfson, Blanco, Liu, Moreno, & Laje, 2006; Olfson, King, & Schoenbaum, 2015; Patel et al., 2005; Pathak, West, Martin, Helm, & Henderson, 2010). A recent study showed that the use of antipsychotics for younger children has declined slightly, while the use for adolescents and young adults continued to increase (Olfson et al., 2015). In 2010, approximately 270,000 prescriptions for antipsychotic medications dispensed to young children, 2.14 million to older children, 2.80 million to adolescents, and 1.83 million to young adults in the United States in 2010 (Olfson et al., 2015). Rates are higher among children enrolled in Medicaid compared to those who are commercially insured (Dosreis et al., 2011; Howie, Pastor, & Lukacs, 2014; Leckman-Westin et al., 2018; Rettew et al., 2015) and children in foster care (Zito et al., 2008) and among adolescent and young adult males (Olfson et al., 2015).

Second generation antipsychotics (SGAs) account for almost all pediatric use of antipsychotics today (Thackeray et al., 2018). SGAs are associated with serious adverse effects such as weight gain and drowsiness and increase the risk of developing hyperglycemia, hyperlipidemia, hyperprolactinemia, and diabetes that are associated with cardiovascular morbidity and mortality (Correll et al., 2009; De Hert, Dobbelaere, Sheridan, Cohen, & Correll, 2011). There is known about their long-term effects of SGAs on child health and the developing brain (Egger, 2010; Zito et al., 2007).

The Federal Drug Administration (FDA)has approved the use of SGAs for children to treat schizophrenia, bipolar mania, irritability associated with autism and Tourette's syndrome. Despite the lack of empirical support for the long-term clinical effects of SGAs to treat children and adolescents without psychotic disorders (Hauck, Lau, Wing, Kurdyak, & Tu, 2017), most pediatric use is for off-label use, particularly for attention deficit hyperactivity (ADHD), depression, and anxiety disorders (Correll et al., 2009; Maher & Theodore, 2012; Olfson et al., 2015). Moreover, young children are likely to be receiving multiple antipsychotic simultaneously to manage their symptoms including stimulants, antidepressants, and/or mood stabilizers (Matone, 2015; Olfson, Crystal, Huang, & Gerhard, 2010; Olfson et al., 2015). Trends are disturbing because overuse is common among populations of young people who are already at risk for poor health outcomes.

The marked increase of FDA-approved and off-label uses of second generation SGAs led to ongoing scrutiny and the development of practice parameters (Schmid, Burcu, & Zito, 2015). There are substantial shortfalls in access to follow-up, metabolic monitoring, and psychosocial services, although children on public insurance were slightly more likely to receive these services (Leckman-Westin et al., 2018). Children who are given SGAs off label are less likely to be monitored carefully (Olfson et al., 2015).

PURPOSE

Growing concern about the use and monitoring of antipsychotic medications for children and adolescents led SAMHSA to convene an expert panel to look at Implementation of Best Practices in Antipsychotic Prescribing for Children and Adolescents. The panel's charge is to develop a SAMHSA Guidance Document for Effective Implementation of Antipsychotic Medication Safety Guidelines in Children and Adolescents. As a member of the expert panel, Family-Run Executive Director Leadership Association (FREDLA) is committed to ensuring that the panel's efforts include the perspective of families. FREDLA conducted a series of four focus groups for family leaders to provide family input into the expert panel. The findings from these focus groups are summarized in this report.

Figure 1. Focus Group Questions

1. In general, how do families feel about giving their children antipsychotic medication?
2. How well are families informed about side effects of antipsychotic medications?
3. What would help families understand the side effects of antipsychotic medications?
4. What have been your experiences, or experiences of families you work with, related to the prescribing of anti-psychotic medication for children and adolescents?
5. Do you know of any practices or systems in place that oversee or monitor best practices for safe antipsychotic prescribing for children and adolescents?
6. Based on your experience as a family leader, how well do prescribers monitor antipsychotic medications and side effects for children?
7. What could help family's to better monitor their child's medication?
8. What non-pharmacological supports or services did your child use before antipsychotic use, if any?
9. Often antipsychotic medications are used during a hospitalization or when the child is in crisis. What experiences are you aware of in these situations?
10. Children on antipsychotic medication are often given medication at school. What have been family's experiences when medication is administered at school? Are teachers and school personnel aware of side effects of these medications? What is the impact on the children of taking antipsychotic medication at school?

METHODS

Before conducting the focus groups, all participants provided informed consent to participate in the focus group and completed a brief survey to obtain demographic information about each of the participants. Three groups were held via conference call during the week of February 26 March 1, 2018. The fourth group was held in person during the University of South Florida Research and Policy Conference on March 5, 2018.

Following a review of the participant protections and purpose of the group, the facilitator asked participants questions about their experiences with prescribers and knowledge about monitoring practices (see Figure 1). Focus groups were recorded and transcribed for thematic analysis.

PARTICIPANTS

Twenty-seven family members and one youth participated in focus groups; 23 identified themselves as the staff of family-run organizations (FROs) of which one was a young adult who was a Youth Coordinator and, five as caregivers. All participants, except for one, were female. Seventy-one percent (N=20) were white, 21% (N=6) were black, and 3% (N=2) were other ethnicities. Participants represented families across the country (see Figure2).

Figure 2. States Represented by Focus Group Participants

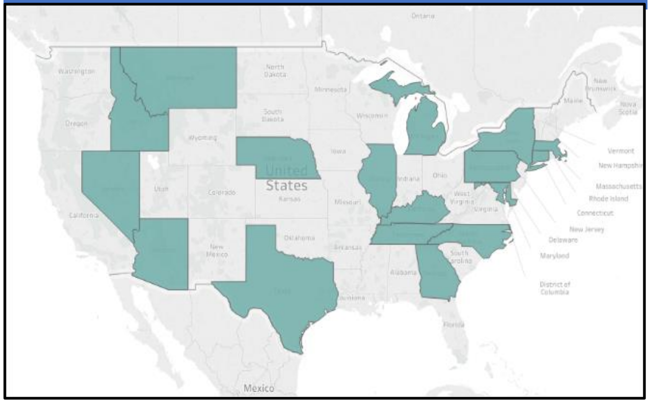

Table 1.
Demographic Characteristics of Focus Group Participants

Total	**28**	**100.0**
Gender		
Female	27	96.4
Male	1	3.6
Race-Ethnicity		
Black or African American	6	21.4
White / Caucasian	20	71.4
Other	2	7.1
Type of Participant		
Caregiver	5	17.9
FRO Executive Leadership	12	42.9
FRO Middle Management	9	32.1
Family Peer Support Staff	2	7.1

DESPERATE FOR HELP:

"You're sort of in a situation where you know, your child is struggling, and you want to do something to help them, but there is very little choice."

"Many families start with alternative and complimentary types of treatment, thinking that if they adjust the diet, or if they do this or that, it's going to work. They're at a point where they've tried and things have not worked. There's a level of desperation."

"We reach out for anything that is going to be helpful for our kids… If we're told that these are going to be helpful for our kids, in our own desperation, it seems like that's the thing that is available to us."

"Once they get into foster care, it seems like these [medications] are kind of the go to's. The parent doesn't feel empowered necessarily to ask a whole lot of questions because they're just working hard to get that kid back in their natural home."

"You get to the point where traditional therapies don't work."

WHAT FAMILIES SAY

" There's very little choice."

Families are uneasy about giving antipsychotic medications to their children, especially young children. They are concerned about the side effects and long-term consequences of use on their children's health. By the time they get to the point where they agree to give their child antipsychotic medications, families have already exhausted other types of interventions and feel desperate for help. Often their family is in the throes of a crisis. Families admitted that even with their concerns about antipsychotic medications, the medications often produce improved behaviors.

"After it works, it's a relief."

Families also said that their children's prescribers were sometimes not aware of other alternatives. When families expressed apprehension about starting medications, they sensed pressure to comply with the doctor's recommendation. Families also felt the pressure of time and that appointments did not allow adequate time to ask all of the questions that they had. Families stated that they needed more information about antipsychotic medications, the specific side effects that their child is most likely to experience, and why this medication is being prescribed.

Families also expressed concern about whether research has enough knowledge about how antipsychotic medications affect the developing brain. They point out that children go through multiple medication trials. One focus group participant gave the example of a child that was put on 21 different medications before she was seven years old. Children are commonly placed on medications at a very young age despite concerns about long-term effects.

“Side effects are just the pits.”

Families reported serious concerns about the side effects of antipsychotic medications, particularly weight gain, gynecomastia, and sleep or drowsiness issues. When their children experienced these side effects, they reported that doctors usually prescribed additional medications to counter the side effects. This resulted in a vicious cycle of multiple medications and frequent changes in medications to the point that families were uncertain as to which medication was causing or treating each specific side effect.

“There's more stigma involved in weight gain often than the actual mental [health concern] itself, which is very unfortunate...”

Families spoke at length about stigma resulting from side effects. The stigma associated with the side effects and the challenges they cause are often greater than the child's mental health concerns. The children who experienced severe side effects often refused to take the medication. Families reported that their children were bullied in school and experienced social isolation because of weight gain and enlarged breasts.

“He went from being a soccer player to a couch potato.”

Families felt that prescribers often minimized their concerns about side effects. Most reported they did not get enough information about side effects when the medication was initially prescribed and didn't get the ongoing support they needed when trying to manage the side effects. One parent attributed the medication's effect on the reduction of behavioral problems to her daughter's inability to stay awake. Families said they sometimes stopped the medication or inconsistently administered medications to their children because of the side effects.

STRUGGLING WITH SIDE EFFECTS:

“There's a lack of real knowledge about how [antipsychotic medication] is going to affect our kids long-term...that's tremendously scary as a parent.”

“It seems that our children are given more and more medications to try to contradict the side effects which the new medications that are [causing] that are now causing other side effects. And so, it's like a vicious circle and we just keep adding meds.”

“There's more stigma involved in weight gain often than the actual mental [health concern] itself, which is very unfortunate ... because kids are mean...when you are not like the rest of them, dealing with mental health issues, side effects, and a weight gain.”

“Families talk about their kids eating themselves through the home, getting up in the middle of the night and how they had to lock the cupboards. Those families clearly weren't getting support in addressing that incredible side effect of increasing appetite.”

MONITORING EXPERIENCES:

“Families tell us that [prescribers] ask you about side effects when they're first prescribing, at the next appointment, and then maybe the next appointment after that and then the question becomes simply, how you are doing?”

“Doctors prescribe multiple medications and make changes to different medications at a time.”

“We were seeing a child psychiatrist for my son and after he got to a certain age, they suggested primary care physician take over on the medications … it was another nervous time for me as a parent. I felt like they were just kind of writing him off.”

“Some families feel targeted. The first line of defense [for children in urban areas and minority children] is to push pills, instead of looking at behavior modifications or any other support systems that can be put in place.”

“We are severely limited on the number of child psychiatrists.”

A common theme within focus group discussions was that prescribers are often not child and adolescent psychiatrists. Prescribers are an important source of information about antipsychotic medications and their side effects. There are many different types of prescribers, including psychiatrists, primary care providers, pediatricians, Advanced Practice Registered Nurses (APRNs), psychologists, and telemedicine. While much of the time a psychiatrist is involved, the psychiatrist may not have a specialization in child and adolescent psychiatry. Frequently, primary care doctors (PCPs) or pediatricians prescribe antipsychotics. Several families referred to their pediatricians having access to psychiatric consultation services and that it was beneficial for all when consultation was available, especially in rural areas. Psychiatrists may also supervise APRNs who can prescribe medications and telemedicine is sometimes used in regions where there is an acute shortage of child and adolescent psychiatrists.

“A lot of parents will get on the web and start looking at meds. They get information and misinformation on social media.”

Focus group participants indicated that families do not feel that they get the support they need from prescribers. Families stated that the prescribers have a limited amount of time with the family preventing prescribers from providing in-depth information about the medication and what to watch for with side effects. They said that prescribers at times used medical language that was technical and difficult for the family to understand, especially when the family was in crisis and needed more time to absorb all the information.

“Doctors may only have 15 to 20 minutes to talk to the family.”

Families related difficulty and frustration trying to reach their child's prescriber and having to wait weeks or months for an appointment. When they did finally get an appointment, it was too short to allow for discussion of their concerns or other options. Although prescribers may have additional staff, such as social workers or nurses, to speak with the family about side effects, there is little time with the prescriber to discuss their concerns about the decision to put the child on medications or to make modifications.

“Most of the information that families receive about side effects is on the piece of paper that’s stapled to the bag when they pick up the medicine at the pharmacy.”

Families stated that the pharmacist who filled the prescription often gave the most helpful information that they received about side effects. The prescription came with an information leaflet that describes warnings and adverse effects. Families reported feeling that they could take more time with the pharmacist than their prescriber to review the pamphlet and answer the family's questions. Unfortunately, this discussion comes after the decision has already been made to put the child on the medication.

Families stated they would like someone to explain how the medication would help their child and to go through the information about side effects more carefully before they leave the doctor's office. Another concern is that the list of potential side effects is often long and includes rarely observed side effects that can be very disturbing. Families wanted guidance on what to look for and how long before their child might manifest any side effects and which side effects are more likely to be observed in their children. Families also stated they wanted to be able to discuss behaviors they see and whether they are side effects of the medications or related to the child's disorder.

“We need case managers with primary care.”

Children are dealing with many other things going on that are side effects of medications. It would be helpful to families if doctors or pediatricians had case managers to help monitor more difficult cases.

The best experience was when the family had a good relationship with the prescriber who took the time to learn about the family history and answer the family's questions. Focus group participants gave some positive examples of prescribing that involved PCPs, pediatricians, and APRNs who have established relationships with the family and/or have greater accessibility. For example, a caregiver in the focus group said that the APRN who worked with her family discussed the family history and noted that alcoholism runs in the family. For that reason, the APRN decided not to prescribe one drug, opting for another medication that had less addictive qualities. The family member was appreciative that the prescriber took the family history into account and provided a clear explanation about her choice of medications. Another focus group participant described working with her PCP who had a well-established relationship with family which had a positive impact on the family.

" The more involvement of parents, the better the monitoring."

The level of monitoring of medication varied considerably and often depended upon the individual prescriber. Monitoring usually involved taking the child's blood pressure and weight, along with periodic blood tests. However, the intervals varied. There was little time during the appointment for caregivers to talk with the prescriber about observed behaviors and side effects. Some PCPs have case managers who discuss side effects and caregivers' concerns with them. Families reported that they would have liked someone to follow-up with them in-between appointments to help them monitor any changes or discuss concerns.

"We need a team approach."

Coordination of care between prescribers and other service providers was limited unless the child was involved with the child welfare or juvenile justice system. Focus group participants indicated that providers for families who receive wraparound services often had better communication than the providers paid through private insurance. Similarly, Medicaid providers tend to communicate better.

Families reported that prescribers were not aware of other services and interventions available. To complicate matters, many private insurance cover medications, but often do not cover other services. Families whose children had Medicaid were more likely to receive services along with medication.

INSURANCE CHALLENGES:

”I would have to get special appeals and permission to keep a certain medication that is actually working. It's unfortunate because if you're showing that something is working, I shouldn't be jumping through hoops to keep it.”

“It becomes a safety concern if [families] can't get the medicines and there are side effects of not having the medication and not having the ability to titrate off. It would just be great if there was a system that was able to …help because it can become a serious issue for families. Simply because there might just be a change in income before other insurance starts, you've got that gap in service.”

“I don't understand how parents can do this because … you have to go through the whole thing every month to get the prescription. Then where we're from, you have to go to the doctor's office and get the prescription given to you by hand and the doctor’s offices close at 5:00.”

Prescribers typically coordinated care through brief reports by phone with other service providers. There were few, if any, opportunities for face-to-face teamwork.

Families also pointed out that they changed prescribers frequently due to, changes in insurance, turnover at clinics, and psychiatrists transitioning care to PCPs. Families felt it was a setback when they had to change prescribers regardless of the reason for the change.

“Families end up paying out of pocket because of gaps in insurance coverage.”

Families with private insurance reported additional challenges. Families stated they feared losing coverage for their child's medication due to restrictions on their insurance coverage. Copays for medication were often very costly and posed a financial burden on the family.

Insurance plans or state formularies sometimes required the use of generic medications rather than brand name drugs. Some families felt that the brand name medication worked noticeably better for their child. Getting approval for the brand name medication required the prescriber submit a request for an exception which could be difficult and take time to get approved. Families described many examples of families paying out of pocket for medications to ensure continuity of their child's medication. One focus group participant reports that in her state, Medicaid providers change almost every year, which resulted in a renewed appeal process.

Families agreed that regulations on antipsychotic medications are a good thing, but the regulations often made it more difficult for families, such as short window when the prescription can be refilled, requirements for prescriptions to be given one month at a time or having to pick up the medication at specified medical sites.

“They’re quick to give out meds.”

Focus group participants from urban areas or minority families expressed strong concerns that medication is prescribed to control their child’s behavior. They often question the need for medications, but they worried that if they did not medicate their children, they will not be able return to school. They feel pressured to medicate their children.   Because many of these families are low income, insurance copays, if required, are a burden and the option to pay out of pocket of medications or services not covered by insurance is often not an option.   These families may be more reluctant to use genetic testing to identify the medications that most effective for their children, due to lack of trust and knowledge about testing.

“Kids are put on high doses of meds in the hospital and when they come out those meds are not changed or evaluated.”

Families described hospitalizations as very disruptive and confusing experiences. During the hospitalization, families reported that their children were given higher doses of antipsychotic medication or their medication was changed. At discharge, there was little or no step down in medications even though their child may not need this dosage when they return home. However, the hospital doctor who prescribed the medications is usually not the same doctor that they see in the community. To adjust the dosage level, they must wait until an appointment with their usual prescriber in the community which could take up to 6 weeks during which their child may be on an unnecessarily higher dosage of medication than warranted. Parents reported that they worried about giving too much medication but did not have an alternative until they could see their child's prescriber.

” Schools don’t have much information about antipsychotic meds or their side effects.”

Families felt pressure to put their child on medications so that their child could stay in school or return to school quickly after hospitalizations. However, most families felt reluctant to let teachers and other school staff know about their child being on antipsychotic medications. Families had strong feeling that schools could misuse information that would further stigmatize their child. Some families also reported that teachers violated confidentiality by asking the child if he/she has taken their medication in front of other students.

Family members expressed concern that school staff members were not knowledgeable about antipsychotic medications and their possible side effects. Due to budget cuts or liability issues, many schools were reluctant to administer medications on site. If schools do not have school nurses, secretaries or other school staff must

DISRUPTIONS DUE TO HOSPITALIZATIONS:

“You have children who were hospitalized and because they're not connected before the hospitalization to any health or behavioral health services, when they get out of the hospital, part of the plan is continuing to meds. The meds maybe at a high dose or more than they need, but they have to wait to get the next appointment [to adjust the dosage], which is maybe six weeks down the line.”

“A kid is hospitalized and hit pretty hard with some high doses of these meds and then comes home on those high doses. There’s not a lot of pieces put into place. Families don’t have a lot of supports and …this leads to yo-yoing back-and-forth in and out of the hospital.”

“Parents don't know what to look for and they're told, we're going to take your kid off these meds and start another med. Let us know you notice anything or if you're worried, but they don't know what that means.”

“Parents don’t feel empowered to ask a lot of questions because they're just working hard to get that kid back home.”

administer medication. Some schools required parents to come to the school to give their children medications.

" I don't think that the average person is aware that there are guidelines for prescribing antipsychotic medications."

Most of the focus group participants were not aware of any guidelines for prescribing antipsychotic medications and were very interested in learning more about guidelines for prescribers. There was a consensus in each of the focus groups that families need to be better informed about evidence-supported practices for prescribing antipsychotic medications to children and adolescents and that this information should be made widely available to families.

"My child hasn't been tested yet, but I'm going to encourage it."

Only a few of the caregivers in the focus groups knew about gene sight testing. Some had used it and were quite enthusiastic, saying that it reduced the number of medication trials their child had to go through. Some staff from family-run organizations suggested that families from minority groups and families from urban areas may be particularly uneasy about gene sight testing. Other focus group participants who were unfamiliar the test expressed deep concerns about privacy issues and how information about a person's DNA might be used. In one focus group, there was a discussion among participants about how gene sight testing works. After which, a young adult commented, "If I can have a DNA test that allows me to be not having to go through the prior authorization process and be approved for medications. I'd do it. I'd take the risk."

RECOMMENDATIONS

1. Before prescribing antipsychotic medication, prescribers should take time to understand the family history and hear the family's concerns about their child. Prescribers should take time to discuss medications, reasons for prescribing them, dosages, and likely side effects with the family.

2. When an antipsychotic medication is prescribed for a child, their family should be given complete information including:
    - The name of the medication (generic and brand names)
    - Reasons for using the medication
    - Side effects of the medication
    - What to watch for and when to contact the prescriber
    - Administering the medication

3. Information should be provided in language for families and available in multiple languages for families whose primary language is not English.

4. Prescribers should contact the family half-way between the start of the medication and their next appointment to check-in to see how the child is doing and to ask about side effects. This interaction should be a one-to-one conversation with the caregiver with ample time to discuss any concerns.

5. Families should be linked to family-run organizations for peer support and assistance in accessing community-based services.

6. Comprehensive information on antipsychotic medication should be available to families on a trusted website that provides information about where to get unbiased and up-to-date information about antipsychotic medications and side effects described in lay terms that families can easily understand. Specifically, families need information about how each medication can affect brain development and which side effects are more likely to be observed and which are not. Families want to see statistics and evidence-based information.

7. A medication-specific checklist should be developed for families to document any behaviors and side effects that they observe between appointments. This checklist could serve as a means of journaling their concerns as they observe them, rather than trying to remember side effects retrospectively during the doctor's appointment. Caregivers can bring this checklist to their appointment, and the doctor should review the checklist with them.

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