Antidepressant prescribing practices for the treatment of children and adolescents.

Supriya K. Bhatia  
University of Nebraska Medical Center

Amy J. Rezac-Elgohary  
University of Nebraska Medical Center, amy.rezac@unmc.edu

Benedetto Vitiello  
National Institute of Mental Health

Michael A. Sitorius  
University of Nebraska Medical Center, masitori@unmc.edu

Bruce A. Buehler  
University of Nebraska Medical Center, bbuehler@unmc.edu

See next page for additional authors

Follow this and additional works at: http://digitalcommons.unmc.edu/com_psych_articles

Recommended Citation

http://digitalcommons.unmc.edu/com_psych_articles/8

This Article is brought to you for free and open access by the Psychiatry at DigitalCommons@UNMC. It has been accepted for inclusion in Journal Articles: Psychiatry by an authorized administrator of DigitalCommons@UNMC. For more information, please contact digitalcommons@unmc.edu.
Antidepressant Prescribing Practices for the Treatment of Children and Adolescents

Supriya K. Bhatia, B.A.,¹ Amy J Rezac, B.A.,¹ Benedetto Vitiello, M.D.,² Michael A. Sitorius, M.D.,¹ Bruce A. Buehler, M.D.,¹ and Christopher J. Kratochvil, M.D.¹

ABSTRACT

Objective: This study evaluates pediatric antidepressant prescribing practices of Nebraska clinicians.

Methods: Surveys were sent in July, 2005, to 1,521 prescribing clinicians throughout Nebraska to assess pediatric antidepressant use along with any practice changes following the U.S. Food and Drug Administration (FDA) “black box” warning issued in October, 2004.

Results: Over half (n = 866) of the clinicians responded to the survey, of which 96.8% reported awareness of the FDA “black box” warning. Of the respondents, 76.9% (n = 666) were prescribing antidepressants to children and/or adolescents. Clinicians reported decreased prescribing frequency for both children (15.5%) and adolescents (36.6%), with 36% having increased referrals to specialists. While 31.9% reported seeing patients more frequently upon initiation of antidepressants, only 7.5% reported weekly visits for the first month of treatment, as recommended by the FDA. Over one fifth (21.9%) reported a caregiver or patient had refused antidepressant medication treatment due to the FDA’s warning.

Conclusion: Clinicians in Nebraska report changes in clinical practice due to the issuance of the FDA “black box” warning, with a decrease in prescribing antidepressants to pediatric patients and an increase in referrals to specialists. Although awareness of the FDA’s warning was evident among clinicians and patients, adherence to recommended guidelines was low.

INTRODUCTION

There has been much debate over the link between antidepressant use and suicidality in the pediatric population (Whittington et al. 2004). The use of antidepressants to treat children and adolescents with major depressive disorder (MDD) had grown steadily in recent years due, in part, to available efficacy data for adults (Kratochvil et al. 2006). It was not until 1997, that evidence of antidepressant efficacy in youths was documented with the first

¹University of Nebraska Medical Center, Omaha, Nebraska.
²National Institute of Mental Health, Bethesda, Maryland.

The opinions and assertions contained in this report are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of Health and Human Services, the National Institutes of Health, or the National Institute of Mental Health.

This research was supported in part by the Spurlock Minority Medical Student Fellowship, American Academy of Child & Adolescent Psychiatry, awarded to Ms. Bhatia.
randomized, placebo-controlled, double-blind study showing the efficacy of fluoxetine in children and adolescents (Emslie et al. 1997). It was around this time that the U.S. Congress passed the 1997 U.S. Food and Drug Administration (FDA) Modernization Act. This Act provided 6-month patent extensions for pediatric studies, which prompted an increase in industry-sponsored MDD studies in children and adolescents. A vigorous response was evidenced by the number of controlled pediatric depression studies conducted subsequently, followed by the publication of several industry-funded trials of fluoxetine, paroxetine, sertraline, citalopram, and escitalopram (Emslie et al. 2002; Wagner et al. 2003; Wagner et al. 2004; Emslie et al. 2006; Rynn et al. 2006; Wagner et al. 2006; Bridge et al. 2007).

In 1998, on the basis of available data, the American Academy of Child and Adolescent Psychiatry (AACAP) published practice guidelines recommending selective serotonin reuptake inhibitors (SSRIs) for the treatment of the acute phase of MDD (Birmaher et al. 1998). Around the same time, The Texas Children’s Medication Algorithm Project also emphasized the use of SSRIs for the treatment of pediatric MDD (Hughes et al. 1999). An increase in pediatric antidepressant use followed, as described by Valuck and colleagues (2004), who reported that the number of adolescents receiving an antidepressant for a new episode of depression grew from 5% in 1998 to 37% in 2002. As noted by Vitiello and co-authors (2006), the total number of adolescents receiving antidepressants grew from 1.8% in 1999 to 4.0% in 2000.

Interestingly, the majority of the pediatric depression trials have failed to demonstrate efficacy on their primary outcome measures. Fluoxetine is the only antidepressant to date that has demonstrated efficacy in at least three pediatric trials, involving 754 youths ages 8–18 years (Emslie et al. 1997; Emslie et al. 2002; TADS Team 2004). Following review of data from the first two trials, the FDA approved fluoxetine for the treatment of pediatric MDD in January of 2003. Currently, fluoxetine remains the only antidepressant approved for the treatment of pediatric MDD.

Not long after the approval of fluoxetine by the FDA, however, the Medicine and Health Care Products Regulatory Agency (MHRA) of the British Department of Health reported that another SSRI, paroxetine, demonstrated a slight increase in suicidal ideation and behavior in children and adolescents with MDD (Hammad et al. 2006). This notice was the first of several issued by the MHRA, and subsequently the FDA, expressing concerns regarding antidepressant use in youths, prompting both regulatory agencies to review available data with a goal of assessing the risk/benefit relationship of these treatments in the pediatric population (Kratochvil et al. 2006).

In 2004, the results of a meta-analysis including 24 controlled clinical trials (approximately 4,400 pediatric patients) of nine antidepressants conducted for various indications were presented at a public hearing in Washington D.C. Although there were no completed suicides within any of the trials, the cumulative risk of spontaneously reported suicidality was 4% for active medication and 2% for placebo (Hammad et al. 2006).

Following the hearing and on the basis of the recommendations of the Psychopharmacologic Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee, the FDA issued a “black box” warning for all antidepressants. The warning stated that an increased risk of suicidality accompanies the use of an antidepressant in the pediatric population for any indication (FDA 2004). Further FDA actions included mandatory distribution of a medication guide with each antidepressant prescription filled for children or adolescents, and the issuance of specific monitoring guidelines. The guidelines stated that upon initiation of antidepressant treatment the clinician should follow up with weekly face-to-face visits for the first 4 weeks, biweekly visits for the next 4 weeks, and then continue with a monitoring visit 4 weeks later (FDA 2005). The frequency of initial visits recommended in the FDA’s monitoring guidelines are compatible with recent findings that indicate the first 1–9 days after initiation of treatment with an SSRI is the critical period for increased risk of suicidal behavior (Jick et al. 2004; Simon et al. 2006, Simon et al. 2007).

Following the FDA’s Public Health Advisory and subsequent warning, the number of anti-
depressant prescriptions written for pediatric patients decreased by about 20% (Rosack 2005; Nemeroff et al. 2007). Recent data from Tennessee show a similar trend, with a 33% decrease in new antidepressant users (Kurian et al. 2007). Although causality cannot be assessed, current Centers for Disease Control (CDC) data indicate that the number of completed suicides in youth under the age of 20 increased between 2003 and 2004 by 18.2% (Hamilton et al. 2007; Rosack 2007). Gibbons and co-authors (2007) recently assessed data from both the United States and the Netherlands, which show an increase in the rate of child and adolescent suicide in the Netherlands to be 49% between 2003 and 2005, and 14% in the United States between 2003 and 2004. Their data also illustrate a concurrent decrease in the number of SSRI prescriptions to be about 22% in both countries, which demonstrates an inverse relationship between the rate of completed suicides and the rate SSRI prescriptions (Gibbons et al. 2007). In addition, recent data show that even the diagnosis of pediatric depression has significantly deviated from historical trends since the issuance of the FDA warning and of those who are diagnosed, a large proportion are not receiving antidepressant treatment (Libby et al. 2007). With suicide as the third leading cause of death among children and adolescents 10–19 years of age, it is important to consider the risk of not treating MDD in the risk/benefit assessment of antidepressant use in youth (Anderson 2002; Hamilton et al. 2007). Additionally, the warning seems to be shifting mental health services from the primary care setting to specialists (Nemeroff et al. 2007). This might lead to increased demand on an already stressed mental health system. These factors highlight the importance of examining pediatric antidepressant prescribing practices following the FDA’s directive, assessing both changes in use of pharmacotherapy, as well as changes in how the medications are monitored in patients.

This study is a systematic review of practitioner patterns of treatment and monitoring of pediatric antidepressant use in Nebraska, with the aim of determining the clinical implications of the FDA warning in this state.

**METHODS**

In July of 2005, 9 months following the placement of the “black box” warning, prescribing clinicians throughout Nebraska completed a self-administered mail-in survey. This survey intended to capture the acute response of prescribing clinicians to the black box warning and address items including: provider frequency of prescribing antidepressants to children and adolescents, comfort with prescribing antidepressants, monitoring and treatment practices, referral patterns and wait time, medication treatment refusal rates, and changes in clinical practice subsequent to the warning. The study was reviewed by the Institutional Review Board at the University of Nebraska Medical Center (UNMC), and determined to be an exempt protocol.

**Sample**

A total of 1,521 prescribing clinicians in Nebraska received the opportunity to complete a survey regarding pediatric antidepressant treatment and monitoring practices. Surveys were distributed by mail in July and August of 2005. Participants included a variety of clinicians with prescribing authority thought to be most likely to treat depressed children and adolescents: all identified child and adolescent psychiatrists, general psychiatrists, pediatricians, family practice physicians, residents and fellows training in these specialties, nurse practitioners, and physician assistants throughout the state.

Contact information for prescribing clinicians in Nebraska was obtained from the Health Professionals Tracking Center (HPTC) at UNMC. The HPTC collects information from professional health-care providers throughout the state by surveying hospitals, clinics, and professionals throughout the year and by means of collaboration with state licensure boards. Some professionals not included in the HPTC, such as those new to clinical practice in Nebraska or those who had not submitted data to the HPTC, were identified and added to the database of prescribing clinicians through information provided by Nebraska Academy of Family Physicians and a UNMC Department of Psychiatry practitioner database. This pro-
vided the most complete clinician database available.

All identified clinicians received a letter explaining the purpose of the study along with a survey. The letter informed participants that the survey was assessing clinician prescribing practices of antidepressants for the treatment of depression in children and adolescents with the goal of the study being to identify new challenges faced by clinicians treating depressed children and adolescents since the issuance of the FDA warning. The clinicians were asked to complete the survey within 2 weeks and return it in an enclosed postage-paid envelope. Tracking numbers were included on each survey, allowing for a certain degree of anonymity but also the opportunity to follow up with those who had not completed the survey within 2 weeks of delivery. Clinicians who did not respond to the initial survey received one additional letter reiterating the above information and providing an additional copy of the survey. No further contact was made with clinicians beyond the second mailing. Once surveys were returned the survey response data was entered anonymously into a secure database.

Survey

Participating clinicians completed the Pediatric Mental Health Resources and Antidepressant Prescribing Practices Survey, which was designed by the study investigators specifically for use in this assessment of prescribing practices in Nebraska. The survey was pilot tested with a small group of clinicians at UNMC to assess readability, comprehension, and clarity of the instrument.

The 13-item survey collected both demographic and clinical information, primarily by means of closed-ended questions with varying formats (categorical, numerical, multiple choice, and Likert-scale). All items referenced antidepressant use and practices for children and adolescents only. The survey items are presented in Table 1.

Data analysis

Each survey returned was entered into a secure database. Population sizes of the practice locations reported were obtained from the Nebraska Department of Economic Development (Nebraska Department of Economic Development 2005). Surveys were then categorized upon entry as exclusively urban or rural localities using the Census Bureau classifications from Census 2000 (U.S. Census Bureau 2005).

Descriptive statistics were used to evaluate frequencies of the individual responses. Responses were analyzed by the clinicians’ specialty and locality (urban versus rural) as well, where applicable. Frequencies and percentages are provided to summarize categorical data, whereas means and standard deviations are provided to summarize continuous variables. All statistical analyses were run using SPSS version 13.0 for Windows (SPSS Inc. 2004).

RESULTS

Sample

A total of 866 surveys (57.5%) were returned containing responses, with 20 surveys returned as undeliverable. Respondent data are presented in Table 2. The surveys represent practices from 140 communities throughout the State of Nebraska. Sixty-two respondents (7.2%) reported practicing in multiple locations. Although practice settings were primarily urban (85.3%), the surveys returned provided a diverse sample of population sizes. Approximately one half (45.7%) of respondents practiced in locations with populations >100,000. However, 21.5% provided services in areas with population sizes of 10,000-100,000, with a significant number (32.7%) practicing in areas of <1,000 people.

Awareness and comfort level

Among the surveys returned (N = 866), nearly all (96.8%) of the respondents were aware of the “black box” warning, which was consistent across specialties [mean 95.0%, standard deviation (SD) 8.2%].

About half (49.2%) of the clinicians described feeling “moderately comfortable” to “comfortable” in prescribing antidepressants to children and adolescents. This comfort level was similar among urban (48.7%) and rural (51.9%) clinicians. Few respondents (8.3%) felt “very com-
<table>
<thead>
<tr>
<th>Item</th>
<th>Possible responses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic items</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Type of clinician: (please check) | Family medicine  
Child and adolescent psychiatrist  
General psychiatrist  
Pediatrician  
Nurse practitioner  
Physicians Assistant |
| What city/town is your clinic(s) located in? (please list) | |
| Type of practice (please check all that apply) | Open-ended  
Private  
Group  
Hospital  
Academic  
Resident physician/fellow  
Other |
| **Clinical practice items** | |
| Are you aware of the FDA black box warning issued for antidepressant use in the treatment of children and adolescents? | Yes/No |
| Before October 2004 (FDA black box warning issued for antidepressants) did you prescribe antidepressants to: | Yes/No |
| Children (<12 years old) | |
| Adolescents (12–18 years old) | |
| Do you currently prescribe antidepressants with the same frequency as prior to October 2004 to: | Yes/No  
If No: More/Less |
| Children (<12 years old) | |
| Adolescents (12–18 years old) | |
| How comfortable do you feel prescribing antidepressants to children and adolescents? (please circle) | 0 = not comfortable to  
5 = very comfortable |
| Please identify the antidepressants you most frequently prescribe for treatment of children and adolescents, please list in order of frequency: | Open-ended (requested top three) |
| Upon initiation of treatment with antidepressants, how frequently is a youth seen at your office in the 1st month of treatment (including the first visit when antidepressant is prescribed)? | 0,1,2,3,4 or >4 |
| How likely are you to refer children and/or adolescents to the following clinicians for mental health treatment since the issuance of the black box warning? | More, Same, Less (for each selection) |
| Child and adolescent psychiatrist | Counselor  
General psychiatrist | Physicians assistant  
Social worker | Nurse practitioner  
Psychologist | Other: __________________________ |
| What is the typical referral wait time for a psychiatrist or child psychiatrist in your area: (please circle) | 0–2 weeks  
2–4 weeks  
4–6 weeks  
6–8 weeks  
>8 weeks |
| Have your treatment practices for children and/or adolescents treated with antidepressants changed since the FDA black box warning? | Yes/No  
If yes how:  
More psychotherapy rather than medications  
Refer more to specialists  
More frequent visits  
More frequent phone contacts  
No longer treats with antidepressants |
| Have patients or guardians refused antidepressant medication treatment due to the FDA black box warning? | Yes/No  
If Yes, what percentage?  
Parent/guardians _____  
Patients _____ |

Note: Table items reflect verbatim the questions listed on the Pediatric Mental Health Resources and Antidepressant Prescribing Practices Survey.
comfortable” in prescribing antidepressants to children and adolescents. Psychiatric clinicians were most likely to report being “very comfortable” (27.2%), followed by pediatric clinicians (8.3%) and family medicine clinicians (5.1%). Approximately one in five (21.9%) of respondents reported experiencing caregivers or patients refusing antidepressant medication treatment due to the FDA “black box” warning. Those clinicians experiencing refusals, report averages of 20.1% (SD 19.2%) of caregivers and 9.1% (SD 15.1%) of patients refusing treatment with an antidepressant, suggesting that parent and youth comfort level was influenced by the warning as well.

**Treatment changes**

The majority (76.9%, n = 666) of responding clinicians were prescribing antidepressants to children and/or adolescents prior to the FDA warning. Of the 666 clinicians who were prescribing to children and/or adolescents prior to the warning, 39.2% were prescribing antidepressants to children (<12 years old) and 99.5% were prescribing to adolescents. Clinicians were prescribing at a lessened frequency following the warning, with 15.5% reporting a decrease in prescribing antidepressants to children and 36.6% reporting a decrease in prescribing to adolescents.

Of the total responding clinicians (N = 866), a few clinicians (4.7%) report no longer treating the children or adolescent patients in their care with antidepressants. Pediatric clinicians reported the largest rate of discontinuation of prescribing antidepressants (11.5%), with fewer family medicine (3.9%) and psychiatric (0.8%) clinicians reporting completely ceasing treatment with antidepressants.

Modifications in monitoring practices were also reported, with 31.9% reporting more frequent patient contacts upon initiation of treatment with antidepressants. Respondents reported an average of 2.15 (SD 0.82) office contacts (including the initial visit) within the first month of treatment. Interestingly, however, only 7.5% of clinicians responded that they were seeing patients weekly for the first month as recommended by the FDA.

Over one third (36.0%), of the responding clinicians described increased referrals to specialists, with 54.5% increasing their referrals to psychiatrists and 39.6% increasing referrals to psychologists, social workers, or counselors. This increase in referrals may be related to the
change in perceived psychiatric referral wait times following the warning. The majority of clinicians (52.1%), both urban (23.8%) and rural (28.3%), perceived that there was an increase in referral wait times by at least 2–4 weeks following the issuance of the warning. Unexpectedly, urban and rural clinicians reported similar wait times across the visit intervals. Further details of practice changes are presented in Fig. 1 and Table 3.

When selecting an antidepressant, clinicians typically preferred prescribing SSRIs for the treatment of children and adolescents. The most frequently prescribed antidepressants are presented in Table 4.

### DISCUSSION

The aim of this study was to evaluate antidepressant prescribing practices for children and adolescents 9 months after the issuance of the FDA “black box” warning. Prescribing clinicians throughout the State of Nebraska were surveyed. The clinicians who responded represent the diversity of treatment providers throughout the state in specialty, location, and community population size. When comparing the results of this study to national data, Nebraska has a similar pattern of physician distribution as compared to many other states with regard to specialty types and practice location (urban versus rural) (American Medical Association 2007).

Awareness of the FDA’s warning was high across specialties and regions, with many clinicians indicating changes in prescribing and monitoring practices due to the “black box” warning. As expected, since the issuance, there has been a decrease reported by clinicians in the use of antidepressants among children and adolescents in the State of Nebraska. Although

<table>
<thead>
<tr>
<th>Table 3. Psychiatric Referral Wait Times (N = 866)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Referral wait time (weeks)</strong></td>
</tr>
<tr>
<td>Not answered</td>
</tr>
<tr>
<td>At the time of survey</td>
</tr>
<tr>
<td>Urban (n = 739)</td>
</tr>
<tr>
<td>Rural (n = 127)</td>
</tr>
<tr>
<td>Prior to FDA warning</td>
</tr>
<tr>
<td>Urban (n = 739)</td>
</tr>
<tr>
<td>Rural (n = 127)</td>
</tr>
</tbody>
</table>
a fair number of clinicians prescribed at a lesser rate, relatively few stopped using antidepressants in children and adolescents altogether. The decrease in the number of clinicians prescribing to children and adolescents is consistent with the national decrease in the rate of prescriptions since the issuance of the warning (Rosack 2005; Nemeroff et al. 2007).

In addition to lowered prescribing frequencies, clinicians reported practice changes as well. The most common practice modifications were increased referrals to specialists and increased visit frequency, although less than 1 in 10 met the FDA recommended guideline for weekly face-to-face visits during the first month of treatment with an antidepressant.

Although few clinicians report the use of psychotherapy in lieu of medications, a number report increasing referrals to psychologists, social workers, and counselors. This may indicate that some clinicians are using psychotherapy as an adjunct to pharmacotherapy, or possibly as a means of increasing visit frequency and safety monitoring when they initiate treatment with antidepressants. This combination of treatments may ease the burden on the prescribing clinician and provide for greater intensity of services, while concurrently providing some level of increased safety monitoring when initiating antidepressant treatment in youth. The Treatment for Adolescents with Depression Study (TADS) demonstrated that the combination of cognitive behavioral therapy and fluoxetine offered the most favorable tradeoff between benefit and risk for adolescents with MDD (TADS Team 2004). This treatment plan may not be feasible for all patients however, as obstacles such as location (availability of psychologists, social workers, or counselors in the area), mental health insurance coverage, and personal schedules may make weekly psychotherapy sessions difficult.

Prospective studies are needed to address the impact of the “black box” warning on patient concerns regarding antidepressant use, actual changes in monitoring practices, changes in clinical care, and impact on clinical outcomes.

On the basis of this retrospective study, the “black box” warning appears to have presented new challenges in providing mental health care. Although clinicians in Nebraska were increasing the frequency of visits, they were not seeing patients weekly during the first month of treatment as initially recommended by the FDA. It is unclear what liability this potentially posed for clinicians who did not specifically follow the FDA guidance, and what impact this could have had longitudinally for care in a state with limited mental health resources. It is of note that in May, 2007, the FDA proposed that the antidepressants’ package inserts be expanded to include an increased risk of suicidality in young adults ages 18–24 (FDA 2007). The new revisions to the package insert now cease to provide monitoring guidelines (FDA 2007). Additionally, they include new language in the warning that state depression or other psychiatric illnesses themselves may be a risk for suicide (FDA 2007).

Interestingly, the survey showed that practitioners in this state were frequently prescribing medications that are not FDA approved for use in children and adolescents with MDD. Although other SSRIs have some support in the literature for the treatment of pediatric depression, only fluoxetine is FDA approved for this
use in this population. It is of note that whereas fluoxetine was the first choice among the psychiatric clinician respondents, for family medicine and pediatric clinicians it was the second and third most common “first choice,” respectively. This finding indicates that factors other than the official label of medication influence prescribing practices in the treatment of mental conditions in children and adolescents.

Effects on comfort level were evident, with only slightly more than half of clinicians reporting that they were comfortable prescribing antidepressants to children and adolescents. Not surprisingly, psychiatric practitioners were the clinicians who felt the most comfortable with prescribing antidepressants to children and adolescents and were the least likely to change their prescribing practices after the warning. Patient comfort level appears to have been affected as well, as a fair number of clinicians report that patients have refused antidepressant medication treatment due to the FDA’s warning. Continued education for the clinician as well as the patient is important, and may aid in increasing comfort levels for both. Additionally, continued education is important to enhance the competency of the clinicians providing care to depressed pediatric patients.

These data indicate that the large majority of clinicians were not following the recommendations set forth by the FDA, but not simply due to an unawareness of the “black box” warning. The findings also indicate that there were concerns, potentially justified, with using these medications. By providing educational opportunities to the general medical community, the hope would be that more clinicians are able to provide appropriate and effective mental health care to children and adolescents. This may help decrease the strain caused by too few child and adolescent psychiatrists available in the community, and increase access to appropriate care. Further research is needed to assess the degree to which sufficient resources are available regionally to treat children and adolescents with mental health issues.

Limitations

Customary mail-in surveys limitations were expected and evident in this study. The survey format does not allow for clarification of answers or questions and respondents are unable to add explanations or additional information. We were unable to compare the demographics of responders and nonresponders due to the anonymity of the survey and of the available clinician database. Additionally, while we were able to sample a diverse group of providers in various community sizes, we only surveyed clinicians in the State of Nebraska; thus, it is possible that the results are relevant only to Nebraska clinicians. Although we have an ample sample size that is fairly representative across specialties, regions, and population sizes, it remains possible that those completing the survey are a biased group, perhaps those that are most comfortable with treating pediatric MDD.

CONCLUSION

The FDA warning and the concerns regarding antidepressant use in youths have presented the mental health community with new challenges in an already stressed health-care system. Scheduling more frequent follow up, increasing use of psychotherapy, and adding telephone contacts between visits may help to provide patients with an improved level of monitoring during treatment with an antidepressant. The most recent FDA changes are quite noteworthy in that they also recognize that there is an inherent risk in having a mental illness itself, which may urge clinicians to re-evaluate the risk/benefit relationship of prescribing antidepressants to youths. In light of the recent changes, patient and parent education remains essential to facilitate adherence, safety, as well as in helping youths and parents understand the importance of working together with the clinician as a team in the treatment of MDD.

DISCLOSURES

Ms. Bhatia has nothing to disclose except for the AACAP fellowship. Ms. Rezac, Dr. Vitiello, Dr. Sitorius, and Dr. Beuler have nothing to disclose. Dr. Kratochvil receives research support from Eli Lilly, McNeil, Shire, Pfizer and
Cephalon, is a consultant for Eli Lilly, Pfizer, Cephalon, AstraZeneca, and Shire, and a member of the Eli Lilly speaker bureau.

REFERENCES


SPSS Inc (2004), SPSS version 13.0 for Windows. Chicago, IL: SPSS Inc.


Address reprint requests to:
Christopher J. Kratochvil, M.D.
Psychopharmacology Research Center
985581 Nebraska Medical Center
Omaha, NE 68198-5581

E-mail: ckratoch@unmc.edu
This article has been cited by:

1. Ann M. Mitchell, Marilyn A. Davies, Christine Cassesse, Ryan Curran. 2014. Antidepressant Use in Children, Adolescents, and Young Adults: 10 Years After the Food and Drug Administration Black Box Warning. The Journal for Nurse Practitioners 10:3, 149–156. [CrossRef]


4. Manish Mittal, Donald L. Harrison, Michael J. Miller, Nancy C. Brahm. 2013. National antidepressant prescribing in children and adolescents with mental health disorders after an FDA boxed warning. Research in Social and Administrative Pharmacy. [CrossRef]


12. References 165–193. [CrossRef]


15. Dale C. Hesdorffer, Andres M. Kanner. 2009. The FDA alert on suicidality and antiepileptic drugs: Fire or false alarm?. Epilepsia 50:5, 978–986. [CrossRef]